No. 22-1877

IN THE
United States Court of Appeals
FOR THE FEDERAL CIRCUIT

EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC,

Plaintiffs- Appellants,

v.

MERIL LIFE SCIENCES PVT. LTD., MERIL, INC.

Defendants – Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA
CASE NO. 4:19-CV-06593-HSG

NON-CONFIDENTIAL OPENING BRIEF AND ADDENDUM OF APPELANTS EDWARDS LIFESCIENCES CORPORATION AND EDWARDS LIFESCIENCES LLC

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September 22, 2022

CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellants Edwards Lifesciences Corporation and Edwards Lifesciences LLC certify the following:

1. The full name of every party represented by me is: Edwards Lifesciences Corporation, Edwards Lifesciences LLC

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is: None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are: None.

4. The name of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

Stradling Yocca Carlson & Rauth, P.C.: Matthew Robert Stephens*
Sheppard Mullin Richter & Hampton LLP: Michelle LaVoie Wisniewski, and Anne-Marie D. Dao
Knobbe Martens Olson & Bear LLP: Brian C. Horne, Ioanna Sophia Bouris, and Adam Rolando Aquino*

*No longer with the firm.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal: None.

6. Information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees): None.

Dated: September 22, 2022 By: */s/ Christy G. Lea*
Christy G. Lea

Attorney for Plaintiffs-Appellants
Edwards Lifesciences Corporation and
Edwards Lifesciences LLC

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This non-confidential opening brief has been redacted to remove information Meril designated as "confidential" during discovery. Edwards asked whether Meril was willing to withdraw its confidentiality designations for appeal and Meril declined. Counsel for Edwards believes that the information has been made public through numerous court filings and court orders, but has erred on the side of caution in designating certain words and phrases as confidential, while adhering to the Court's 15-word limit.

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OTHER AUTHORITIES

INDEX TO APPENDED MATERIALS

The following U.S. patents are included in the Joint Appendix but not included in the Appended Materials because the content of the patents is not relevant to the determination of this appeal.

U.S. Patent No. 10,292,817 (Appx84-110);
U.S. Patent No. 9,393,110 (Appx111-152);
U.S. Patent No. 9,119,716 (Appx153-189);
U.S. Patent No. 6,878,168 (Appx190-198); and
U.S. Patent No. 10,053,256 (Appx199-207).

STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5(a), no other appeal in or from the same civil action in the lower court was previously before this or any other appellate court.

Pursuant to Federal Circuit Rule 47.5(b), counsel is unaware of any other pending cases that will directly affect, or will be directly affected by, the Court's decision in this appeal.

JURISDICTIONAL STATEMENT

The district court had jurisdiction in this patent infringement case under 28 U.S.C. §§ 1331 and 1338. This Court has jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(1).

On May 18, 2022, the district court entered final judgment after previously dismissing Edwards' patent infringement claims on summary judgment. Edwards timely filed its notice of appeal on June 1, 2022.

STATEMENT OF THE ISSUES

Whether the district court erred in granting summary judgment that Meril's alleged patent infringement for importing medical devices for use at a commercial industry conference was exempt under the safe-harbor provision of 35 U.S.C. § 271(e)(1) where:

(a) the district court erroneously failed to credit contemporaneous evidence creating a triable issue of fact as to whether Meril imported the devices solely for uses reasonably related to U.S. FDA submissions,

(b) the district court erroneously failed to draw reasonable inferences in favor of the non-movant Edwards, relying instead on self-serving and uncorroborated declarations from Meril employees who lacked personal knowledge of the material facts declared, and

(c) while purporting to apply an objective standard to determine whether Meril imported the devices solely for uses reasonably related to U.S. FDA submissions, the district court erroneously relied on Meril's alleged purpose for the importation?

STATEMENT OF THE CASE

Edwards filed its Complaint in the United States District Court for the Northern District of California on October 14, 2019, alleging Meril infringed three of Edwards' patents: U.S. Patent Nos. 10,292,817, 9,393,110, and 9,119,716. Appx27-28. The '817 patent relates to methods of making implantable prosthetic heart valves. Appx84-110. The '110 patent relates to an assembly for implanting the heart valves, including a delivery device and prosthetic heart valve. Appx111-152. The '716 patent relates to a delivery device for implanting a prosthetic heart valve. Appx153-189. Edwards alleged that Meril infringed the '817 patent under 35 U.S.C. § 271(g) and the '110 and '716 patents under 35 U.S.C. § 271(a) by importing its Myval heart valve and delivery system (the "Myval Devices") into the United States.

Meril moved to dismiss the patent infringement causes of action, arguing that its importation was protected by the safe harbor of 35 U.S.C. § 271(e)(1). *See* Appx29-30; Appx208-214. Section 271(e)(1) provides that "[i]t shall not be an act of infringement to . . . import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates" drugs or medical devices. Meril alleged that it imported the Myval Devices for display at a medical conference in order to recruit clinical investigators to perform clinical studies. On February 18, 2020, the district court denied Meril's motion. Appx208-214. In denying Meril's motion to

dismiss, the Court held that "[n]ot all activities performed prior to FDA approval" fall within the safe harbor exemption. Appx211 (citing *Amgen Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 852 (Fed. Cir. 2009) (*Amgen I*) (question of fact as to whether safe harbor applies where evidence suggests that some studies were conducted at the request of the marketing department for brand recognition purposes)). The district court also held that "commercial intent" may be probative of whether an otherwise infringing act is "solely for uses reasonably related" to a regulatory submission. Appx213 (citing *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1340 (Fed. Cir. 2019) (*Amgen II*) (upholding jury's finding that manufacturing of batches for commercial inventory was not exempt under Section 271(e)(1)).

On April 6, 2020, Edwards filed a First Amended Complaint alleging infringement of two additional patents: U.S. Patent Nos. 6,878,168 and 10,053,256. Appx215-252. Both patents relate to methods of treating bioprosthetic tissues used in heart valves to mitigate post-implantation calcification. Appx190-198; Appx199-207. Edwards alleged that Meril infringed both patents under 35 U.S.C. § 271(g) by importing its Myval heart valve into the United States. Appx246-247.

Shortly thereafter, Meril moved for summary judgment based on its § 271(e) safe harbor defense. Appx272-293. Meril again claimed, through declarations, that it imported the accused devices to use at a U.S. medical conference for the

purpose of recruiting investigators (physicians) to perform clinical studies, allegedly for submitting data to the United States Food and Drug Administration ("FDA"). Appx294-296; Appx369-374. Edwards submitted contemporaneous evidence that contradicted Meril's alleged purpose and use, including: (a) evidence that Meril imported the Myval Devices solely for use as commercial sales tools at a trade show, unrelated to any clinical or regulatory efforts; and (b) evidence that the clinical study planned by Meril at the time of importation was a post-approval European study that was unrelated to FDA submissions. *See* Appx568-592. Nonetheless, on October 16, 2020, the district court granted Meril's motion for summary judgment of no infringement based on the safe harbor exemption. Appx1-20. Following a settlement on all other causes of action in the case, the district court entered final judgment on the patent infringement claims on May 18, 2022. Appx21-22.

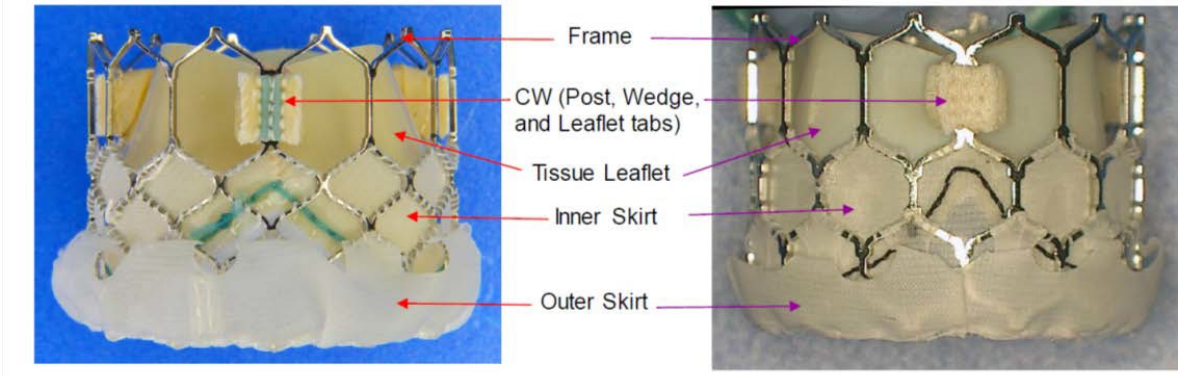
Edwards now appeals the district court's grant of summary judgment on Meril's § 271(e)(1) safe harbor defense.

STATEMENT OF FACTS

Edwards is a leading innovator and supplier of medical devices for the treatment of heart disease and is world renowned for its artificial heart valves. Among its best-known products are its line of SAPIEN® transcatheter prosthetic heart valves and related delivery systems. Edwards revolutionized the industry when it developed and commercialized a prosthetic heart valve that could be delivered via catheter while the heart is still beating. Edwards' innovations have saved hundreds of thousands of patients from having to undergo traumatic open-heart surgery, which requires stopping the patient's heart and placing the patient on a heart-lung machine to keep them alive during the procedure.

Meril attempted to capitalize on Edwards' innovation and success by copying the SAPIEN product design. Appx222-225. Meril's transcatheter heart valve, which it calls "Myval," is nearly identical to Edwards' SAPIEN valve:

Edwards SAPIEN 3 **Meril Myval**



Id. Meril makes its Myval transcatheter heart valve and the accompanying Navigator delivery system (collectively "Myval Devices") in India. Appx370. Edwards brought this lawsuit to enforce its patent rights and protect its innovation in the SAPIEN valves.

On September 24, 2019, Meril imported two Myval Devices into the United States and to San Francisco where the Transcatheter Cardiovascular Therapeutics Conference ("TCT Conference") was scheduled to begin on September 25, 2019. Appx372. Two days after the conference had begun, on September 27, 2019, a Meril employee named Nilay Lad carried the Myval Devices to the convention hall at the TCT Conference. Appx370, Appx373-374. Meril claims that it never removed the Myval Devices from the bag in which they were transported and that it never showed the Myval Devices to any conference attendees. Appx374. On September 28, 2019, Mr. Lad handed the bag containing the Myval Devices to another Meril employee named Sanjeev Bhatt who transported them to Europe. Appx374; Appx295-296.

In moving for summary judgment under the safe harbor statute, Meril relied on declarations from those two employees, Nilay Lad and Sanjeev Bhatt. Appx369-374; Appx294-296. Lad declared that Meril imported the Myval Devices for display at the 2019 TCT Conference, where Meril allegedly intended "to recruit clinical researchers for the clinical studies that would be necessary for FDA approval" of the Myval Devices. Appx371; Appx296. However, the

contemporaneous evidence discussed below contradicts that claim, and supports the conclusion that Meril imported the Myval Devices solely as a commercial sales tool. Moreover, the evidence supports the conclusion that the clinical study that Meril references as part of its defense was a post-approval European study that was unrelated to FDA approval.

I. THE MYVAL DEVICES HAD ALREADY RECEIVED REGULATORY APPROVAL IN EUROPE BEFORE THEY WERE IMPORTED INTO THE UNITED STATES

Meril began clinical trials for the Myval Devices in India in June 2017 and received regulatory approval for the Indian market on October 31, 2018. Appx370. As is typical with clinical trials for regulatory approval, Meril conducted a single-arm clinical trial called Myval-1 in Indian hospitals. Appx657; Appx335. A single-arm clinical trial is one involving a single device, without any comparison to other devices. Appx452. Based on that same single-arm clinical trial, the Myval Devices received CE certification in April of 2019, which allowed Meril to market and sell the Myval Devices for use in Europe. Appx370. Thus, by the time Meril imported the Myval Devices for the TCT Conference in September 2019, they had already been approved for use by physicians in Europe. *Id.*

II. MERIL IMPORTED THE MYVAL DEVICES TO THE TCT CONFERENCE AS COMMERCIAL SALES AND MARKETING TOOLS

The TCT Conference is the leading conference in the field of interventional cardiology. With over 11,500 attendees, including thousands of physicians from

Europe and other countries outside the United States (Appx735-737), TCT provides companies with "unparalleled marketing opportunities" to "increase visibility of products and services":

Appx730. The 2019 TCT Conference was held in San Francisco from September 25 to September 29. Appx729.

Meril took advantage of the TCT marketing opportunities. It sent "invitations" drafted by Meril's marketing personnel to over 3,000 TCT registrants prior to the Conference, encouraging them to visit Meril's tradeshow booth at TCT and "Experience Meril's technologies & hands-on simulation of Meril's TAVR system — Myval THV." Appx884-886; Appx888; Appx616. As shown below, the invitation did not mention any purported need for, or recruitment of, clinical investigators:

Appx885.

Meril also engaged in other marketing efforts for Myval leading up to TCT. On September 14, 2019, Meril sent an email blast to thousands of physicians and industry professionals registered to receive such communications regarding TCT 2019, including hundreds based in Europe. Appx670; Appx889-893; Appx570; Appx745-748. Like Meril's earlier marketing invitation, it too invited recipients to "have hands-on and VR sessions on Meril's TAVR system – Myval™ THV." Appx747; Appx890-892. This email blast touted the Myval Devices as "ensuring

predictable clinical safety and efficacy outcomes," and did not mention anything about clinical trials or recruiting clinical investigators:

Appx746-748. In contrast, less than two months later, Meril sent an e-blast to attendees of the London Valves conference in Europe, in which it expressly advertised "9 Landmark Trial investigator meetings." Appx964-965.

Meril's marketing materials also advertised to thousands of TCT attendees that Myval was "CE Approved," meaning it could be sold commercially in Europe. Appx570; Appx745-47; Appx889-891. Meril also updated its Myval brochure specifically for the TCT conference, again touting its CE Approval and even providing "Myval – THV Ordering Information." Appx825-826, Appx852.

In furtherance of its plan to sell Myval Devices to European physicians at the TCT Conference, Meril executives, in consultation with its lawyers, drafted and announced "Instructions for TCT 2019 for Myval THV System" to its twenty employees who attended TCT. Appx632; Appx907-909. With respect to the Myval Devices imported to TCT, Meril instructed its employees at TCT as follows:

- "Do not make any sales or offers for sale at the conference, or while in the United States for the [redacted]. **You can [redacted] for other countries**." (Emphasis added.)
- "Do not carry too many demo units."

CONFIDENTIAL MATERIAL REDACTED

Id. Meril employees were thus encouraged to [redacted] Myval Devices for commercial use in other countries where Myval Devices were approved. The Instructions also refer to the imported Myval Devices as "demo units," which indicates that they were to be used as commercial sales tools by Meril's salesforce—not as recruiting tools by its clinical trial team. See *infra* Statement of Facts § III. The relatively few Myval demo units thus supported Meril's sales efforts to hundreds, if not thousands, of physicians from "other countries." Appx909; Appx735-737. The Instructions for Myval also stated: "If possible, refer discussions of pricing, delivery, and other commercial topics to representatives outside the US for the [redacted]." Appx909. Most importantly, Meril's Instructions, like its invitation, email blast and brochure, did not mention a single word about recruiting clinical investigators at TCT. Appx907-909; Appx882; Appx884-886; Appx890-893; Appx746-748; Appx825-853.

Moreover, Mr. Lad testified that it was Meril's marketing team that decided they would do hands-on sessions with the Myval Devices using a simulator. Appx640. Mr. Lad, an employee with no regulatory or other responsibilities relating to Myval, brought the Myval Devices to the conference on September 27, where the purported plan was for marketing personnel to demonstrate them with a simulator. Appx612-613, Appx640; Appx373-374. The demonstrations were not to be limited to any particular persons, and "anybody who wants to come can do the hands-on session." Appx640. However, according to Meril's witnesses, Meril

never displayed the Myval Devices at TCT because the simulator malfunctioned. Appx374. Meril then allegedly opted not to show the Myval Devices without the simulator, even though it had shown the Myval Devices, without a simulator, at previous conferences. Appx570; Appx874-879; Appx614-615; Appx618-619.

III. THE IMPORTATION OF MYVAL DEVICES WAS UNRELATED TO ANY RECRUITING OF CLINICAL INVESTIGATORS

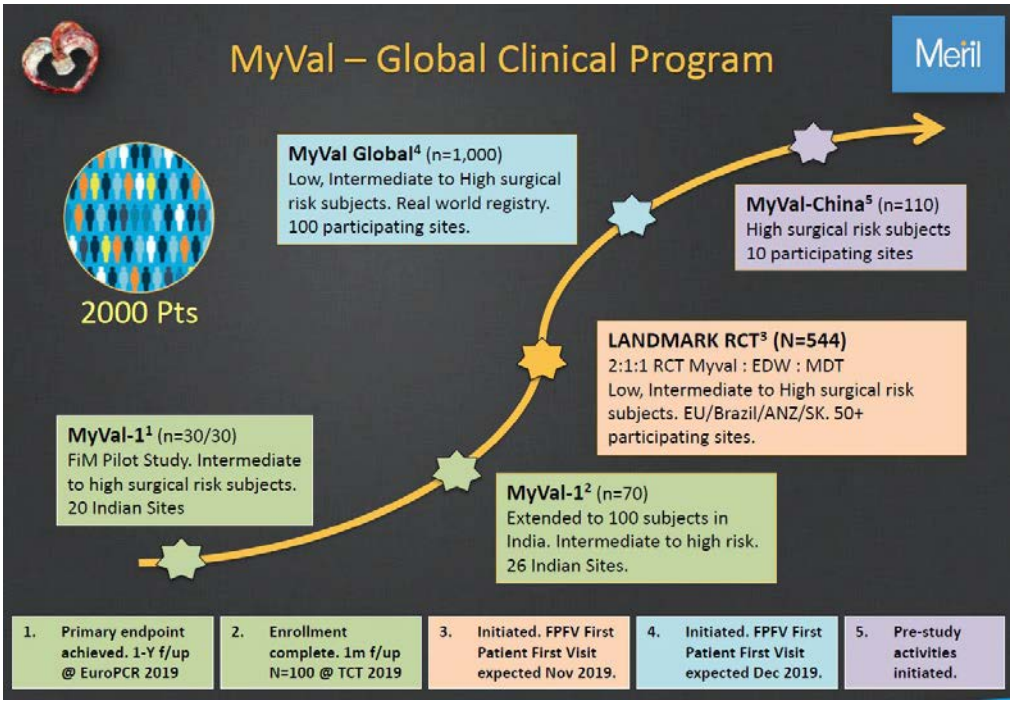
On the evening of September 26, 2019, Meril held a dinner at a restaurant for prospective clinical investigators for its Landmark Trial. Appx618; Appx647. It was the only meeting Meril held for clinical investigators at TCT 2019. Appx647. Oddly, despite claiming that it imported the Myval Devices to recruit clinical investigators, Meril never even planned to bring them to this meeting, and did not do so. Appx618. In fact, Meril's communications regarding this meeting never mention any sample Myval Devices or hands-on sessions with Myval. Appx571; Appx961; Appx774-783.

In sum, while contemporaneous documentary evidence shows that Meril's importation of the Myval Devices was to support commercial sales efforts, no contemporaneous evidence ties the importation to the recruitment of clinical investigators, let alone clinical investigators for a study relating to FDA submissions.

IV. MERIL PLANNED TO COMPARE THE MYVAL DEVICES WITH OTHER LEADING DEVICES IN EUROPE TO BOOST COMMERICAL SALES

Shortly after receiving CE-mark regulatory approval in Europe in April 2019, Meril announced plans to conduct its "Landmark" Trial, a post-approval comparative clinical trial in Europe. Appx298, 334 (Myval – Global Clinical Program as of March 30, 2019; Appx588-589; Appx912 (Myval – Global Clinical Program as of May 2019). Meril sought to compare Myval with the market leading devices in Europe: Edwards' SAPIEN valves and Medtronic's CoreValve Evolut valves. Appx657. A Meril brochure seized in May 2019 at the EuroPCR industry conference in France included a slide on Meril's "Myval – Global Clinical Program," including the planned Landmark Trial. Appx588-589; Appx912.[1] As shown, the Landmark Trial was to include clinical sites in the EU, Brazil, Australia/New Zealand, and South Korea, but **not the United States**.

[1] The seizure was the result of a proceeding in France alleging that the Myval Devices infringed Edwards' European patents. Appx613.



Appx912. At the time it planned the Landmark Trial as an outside-the-U.S. ("OUS") study, Meril knew FDA approval would require U.S. trial sites. Appx677; Appx716. Thus, the Landmark Trial was never an "FDA clinical trial" as claimed by Meril. Appx372-373 (Lad Decl. ¶¶ 12, 15).

In a brochure published in August 2020, long after Meril imported the Myval Devices to the TCT Conference in the United States, Meril continued to present the Landmark Trial as a comparative, three-arm trial to be conducted entirely outside the United States, starting in late 2020. Appx591; Appx915. Thus, Meril planned its Landmark Trial after the Myval Devices were approved in Europe in April 2019, and never planned to include U.S. clinical sites in that post-approval trial. Moreover, no contemporaneous evidence shows any communications with U.S. clinical investigators or clinical sites resulting from

Meril's purported "recruiting" efforts at TCT. Appx709; Appx961; Appx774-783; Appx1218.

V. MERIL'S RECRUITMENT OF CLINICAL INVESTIGATORS IN EUROPE DID NOT INCLUDE DEMONSTRATING THE MYVAL DEVICES

Meril began marketing its Myval Devices for sale in Europe after CE approval in April 2019. Appx370. In addition, Meril's Senior Vice President, Sanjeev Bhatt, traveled around Europe recruiting clinical investigators for the Landmark Trial. Appx569; Appx719, 721-727. Bhatt's primary recruitment tools were PowerPoint presentations. He testified that "[t]he slide deck is the most meaningful way to have a conversation with a clinician. It's the best thing that you can do." Appx669. Notably, Bhatt admitted that he tries to avoid using sample devices when recruiting clinical investigators, and he never used a simulator to demonstrate a sample device to recruit an investigator. *Id.* Bhatt's admission further supports that Meril imported the Myval Devices not for use in recruiting clinical investigators but for use as sales tools for its TCT marketing team. Appx884-886; Appx616; Appx890-892; Appx372; Appx397-399; Appx907-909.

VI. MERIL'S PRESENTATIONS ON THE LANDMARK TRIAL CONFIRM IT WAS TO TAKE PLACE OUTSIDE THE UNITED STATES

Meril's claim that it planned to recruit U.S. clinical investigators at TCT 2019 for the Landmark Trial is contradicted by a wealth of contemporaneous evidence. Meril's own TCT presentation reported that the Landmark Trial was to

be conducted entirely outside the United States. Appx675; Appx923, 946, 953. Later presentations, such as one dated November 17, 2019, also reported the Landmark trial as an OUS study. Appx969, 996-997. Indeed, the brochure on Meril's website as of August 3, 2020 (which was continually updated) advertised the Landmark Trial as an OUS study with 50+ sites in Europe, Australia, and New Zealand. Appx591; Appx915-916. It acknowledged that the first patient would not be enrolled in the trial until late 2020, at the earliest. *Id*. The evidence thus supports the conclusion that the Landmark Trial was not reasonably related to FDA regulatory approval, which Meril knew would require U.S. trial sites. Appx677; Appx716.

VII. THE IMPORTATION OF MYVAL DEVICES WAS UNRELATED TO MERIL'S VOLUNTARY "PRESUBMISSION" TO THE FDA

On August 23, 2019, a few months after the seizure at a European conference, Meril [redacted] about importing Myval Devices to the September 2019 TCT Conference in the United States. Appx610-612; Appx869-873. From late August to early September, Meril [redacted] regarding the importation of Myval Devices for use at TCT 2019. *Id*.

After starting those [redacted], Meril began communicating with the FDA and with a regulatory consulting firm called CardioMed. On September 3, 2019, Meril inquired about the clinical data needed for an FDA presubmission. Appx388. On September 5, 2019, Meril informed CardioMed that it was planning

an OUS study (the Landmark Trial) with no plans for any investigation sites in the United States. Appx1021-1022. Meril also sent a general email inquiry to the FDA mentioning its planned OUS study and asking about the requirements for a "Pre-submission." Appx1015-1019. On September 9, 2019, the FDA responded to Meril's general inquiry that pre-submissions are entirely voluntary and merely used to get FDA feedback on planned studies. Appx1015.

On September 23, 2019, long after Meril advertised that it would demonstrate Myval Devices at TCT, CardioMed advised Meril that the FDA requires clinical trial sites in the United States, and would not approve a heart valve based on an OUS study. Appx1025-1026; Appx1029-1030. CardioMed recommended that Meril propose two studies: its OUS (Landmark) study and a separate single arm study in the United States, but cautioned that Meril could only perform a domestic study after receiving an Investigational Device Exemption (IDE). Appx1026; Appx1032. No evidence suggests that Meril has ever attempted to obtain an IDE from the FDA regarding the Myval Devices. Rather, Meril admitted that it was nowhere near applying for the IDE, and did not have a single U.S. investigation site lined up. Appx676-677, 691-692. At the time of its importation of Myval Devices for TCT in September 2019, Meril had only engaged in exploratory communications with the FDA and its consultant regarding a presubmission.

On November 9, 2019, weeks after TCT, Meril informed CardioMed that it was changing its clinical study strategy. Appx1036-1037. Rather than pursuing the recommended two-study strategy, Meril would propose only its Landmark study but would propose to include both OUS and domestic sites, with one third of the study subjects in the United States. *Id.* CardioMed immediately advised that the FDA would not accept a study design with less than 50-60% U.S. enrollment and it did not want to risk its reputation signing a presubmission seeking guidance on such a study. Appx1036; Appx1047; *see also* Appx677; Appx716 (acknowledging that Meril knew that the FDA would require a significant cohort of U.S. patients for any FDA clinical trial).

Meril ultimately filed its presubmission on December 4, 2019, months after the importation of Myval Devices for TCT. Appx374; Appx445-495. Against CardioMed's advice, Meril sought guidance on a proposed study with only one third of the subjects in the United States. Appx459. As expected, the FDA responded to Meril's voluntary presubmission that the proposed clinical study would not generate adequate evidence for the FDA because it included too few domestic patients. Appx1049-1050. There is no evidence that Meril ever submitted any filing required by the FDA for the approval of a medical device, such as an application for an IDE or premarket approval (PMA)—and certainly no

evidence of any such application submitted prior to TCT 2019. To the present day, the Landmark Trial does not include U.S. clinical investigators or study locations.[2]

VIII. THE DISTRICT COURT'S SUMMARY JUDGMENT ORDER

On October 16, 2020, the district court granted Meril's motion for summary judgment, holding that its importation of Myval Devices was exempt from patent infringement under the safe harbor of 35 U.S.C. § 271(e)(1). Appx1-20. The district court held that "the safe harbor inquiry focuses on acts or uses, and not on purposes, intent or motive." Appx7. It also held that the statute "extends even to activities the 'actual purpose' of which may be 'promotional' rather than regulatory, at least where those activities are 'consistent with the collection of data necessary for filing an application with the FDA.'" Appx7. The district court did not explain how its holding squares with § 271(e)(1), which requires that the infringing act be "**solely** for uses reasonably related to the development and submission of information under a Federal law." (Emphasis added.)

The district court also held that the statute, despite stating "solely for uses," does not require an "actual use." Appx8. The court held that as long as the infringing importation is "reasonably related to obtaining FDA approval," then the

[2] https://clinicaltrials.gov/ct2/show/NCT04275726?term=myval&draw=2&rank=2. *See, e g.*, *Bryant v. Carleson*, 444 F.2d 353, 357-58 (9th Cir. 1971) (taking judicial notice of developments since the appeal, including relevant administrative action of the Administrator of the United States Department of Health, Education and Welfare); *Kirby v. Pa. R.R. Co.*, 188 F.2d 793, 795 (3d Cir. 1951) (taking judicial notice of a paper describing the operation of the Railroad Adjustment Board, acknowledging that paper was "not in the record").

safe harbor applies. Appx8. The district court never explained how an importation could be deemed "reasonably related to obtaining FDA approval" without considering either the subjective intent of the importer or the importer's actual use of the device after importation.

Citing this Court, the district court held that "demonstrations at medical conferences are covered by the Section 271(e)(1) safe harbor" as a matter of law. Appx8. And because "transporting a device to a medical conference is a necessary and predicate act for displaying the device," the district court reasoned that importing the device for display at a medical conference is also exempt under the safe harbor, regardless of intended purpose or actual use. Appx9.

Crediting the testimony of Meril's witnesses, the district court found that "Meril had taken significant steps towards obtaining FDA approval." Appx9. It failed to credit Edwards' contrary evidence showing that, by the time of the importation, Meril had only engaged in exploratory communications regarding an entirely voluntary presubmission that was for guidance only, was not required for FDA approval, and did not even begin the FDA approval process. Appx1015-1019. Instead, the district court found that Meril's OUS Landmark trial was reasonably related to FDA approval, because FDA approval **can be** supported by clinical trials that include patients both within and outside the United States. Appx9, n3.

Throughout its Order, the district court repeatedly credited Meril's declarations and deposition testimony, even when contradicted by contemporaneous documents and when reasonable inferences could be drawn in favor of Edwards. The district court repeatedly stated that Edwards did not dispute Meril's facts, when the record shows otherwise. Edwards submitted 45 exhibits that disputed Meril's version of the facts. *See* Appx568-592. Edwards' brief contained entire sections disputing Meril's version of the facts, including:

A. The Contemporaneous Evidence Shows that Meril's Importations Were Not for the Purpose of Recruiting Clinical Investigators for FDA Approval,

C. The Landmark Trial Was Not an "FDA Clinical Trial," and

D. After-the-Fact FDA Activities Cannot Manufacture a Safe Harbor Defense.

Appx556-560. The district court never addressed the documents submitted by Edwards and cited in these sections, nor did it draw all reasonable inferences from them in Edwards' favor as the non-movant.

Indeed, the district court placed heavy emphasis on its finding that Meril "did not sell or offer to sell" its Myval Devices at TCT 2019—a fact it called "undisputed." Appx4-5, 10, 15. But as explained above, that very fact was refuted by Meril's own documents submitted by Edwards in opposition to Meril's motion. *See, e.g.*, Appx907-909 ("You can [redacted] for other countries."). And the

separate infringing act of importation does not require a sale or offer to sell in any event.

The district court also held that Meril's purpose for importing the Myval Devices is irrelevant, but found that, if purpose were relevant, Meril's purpose was to support clinical trials to seek premarket approval from the FDA. Appx14. Again, the district court failed to address any of the numerous documents Edwards submitted showing that Meril's purpose for bringing the Myval Devices to TCT was solely to support commercial sales offers to European physicians, not to recruit clinical investigators for an FDA trial. *See* Appx14-15.

SUMMARY OF THE ARGUMENT

The district court erred in three respects when granting summary judgment in favor of Meril and holding that its importation of Myval Devices to TCT was within the safe harbor defense. First, in determining that the importation was solely for uses reasonably related to an FDA submission, the district court failed to view the evidence in the light most favorable to Edwards by ignoring substantial contemporaneous evidence from which a reasonable jury could conclude otherwise. The contemporaneous evidence supported a reasonable conclusion that Meril imported the Myval Devices solely for use as a commercial sales tool, and not for use in recruiting clinical investigators. This contemporaneous evidence includes:

- Marketing materials advertising the Myval Devices as "CE Approved" and inviting TCT attendees to "hands-on" demonstrations of the Myval Devices – without any mention of clinical trials or clinical investigators. Appx 372; Appx397-399; Appx570; Appx746-748; Appx881-882; Appx884-886; Appx890-893; Appx825-853.
- Instructions to Meril sales personnel attending TCT that they could use Myval "demo units" while [redacted] the Myval Devices for use outside the United States. Appx632; Appx907-909. Again, these Instructions, which are the most probative evidence of Meril's

planned use for the imported Myval Devices, never mention clinical trials or clinical investigators.

- Meril's admissions that it never planned to use the imported Myval Devices at its only investigator meeting at TCT, and that it rarely if ever used sample devices to recruit clinical investigators. Appx618; Appx669.

Even if the importation of Myval Devices were somehow related to the Landmark Trial, the district court compounded its error by also accepting Meril's argument that its Landmark Trial was reasonably related to FDA approval, despite contrary evidence that:

- The Landmark Trial was a post-EU-approval study to be conducted in Europe to compare the Myval Devices to the leading devices in the European market. *See* Appx9 n.3.[3]
- When Meril planned the Landmark Trial as an OUS trial, Meril knew FDA approval would require a trial with U.S. sites. Appx677; Appx716.

[3] As correctly noted by the district court, the Landmark Trial was primarily a European trial, but with a few sites in other foreign countries. Post-approval and foreign studies are not within the safe harbor absent "a clear indication that [foreign clinical] work was submitted, or to be submitted, to the FDA." *NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 208-209 (D.N.J. 1994) (foreign clinical work); *Amgen I*, 565 F. 3d at 852-53 (post-approval comparative studies).

- Meril first mentioned an FDA presubmission only after deciding to import Myval Devices to TCT and then [redacted] about the importation. Appx884-886; Appx616; Appx1015-1016; Appx609-610; Appx869-873.
- Meril's presubmission to the FDA was entirely voluntary and for guidance only, was not required for FDA approval, and did not even begin the FDA approval process. Appx1015-1019. Even assuming Meril's FDA presubmission was *bona fide*, it was still years from requiring clinical investigators in the United States. *See* Appx676-677, 691-692.

This evidence thus supports the conclusions that Meril imported the devices for reasons unrelated to the Landmark Trial, and that the Landmark Trial was not reasonably related to seeking FDA approval.

The district court also erred by improperly relying on self-serving declarations of Meril employees who lacked personal knowledge of the facts declared, and which are contradicted by the contemporaneous evidence. In ruling that Meril's importation of the Myval Devices "was related to the submission of information to the FDA" the district court relied entirely on the Declaration of Nilay Lad. Appx10 (citing only Appx372-374 (Lad Decl. ¶¶ 13-15, 17)). But Mr. Lad's job responsibilities had nothing to do with FDA or other regulatory submissions, recruiting clinical investigators, selling Myval Devices, or

transporting devices to trade shows. And Meril made the decision to import Myval Devices for "hands-on demonstrations" at TCT long before Lad claimed the importation decision was made. *Compare* Appx881-882, Appx884-886 (invitations for "hands-on demonstrations), *and* Appx890-893, *with* Appx602-603. Nevertheless, the district court credited Mr. Lad's testimony that Meril imported the Myval Devices to recruit clinical investigators for a so-called "FDA clinical trial," despite the contrary evidence that the importation had nothing to do with clinical trials, and that the only clinical trial planned by Meril had nothing to do with the FDA. Appx10 n.4.

Finally, although the district court purported to apply an objective standard to determine whether Meril's importation was solely for uses reasonably related to FDA submissions, it erroneously relied on Meril's representations concerning its alleged purpose for the importation. The district court held that Meril's intent for the importation was irrelevant, and thus purported to rely only on Meril's actual use of the Myval Devices. Appx 15. But lacking evidence of any actual use after importation, the district court purported to consider only the importation itself. The district court reasoned that "transporting a device to a medical conference is a necessary and predicate act for displaying the device" to recruit clinical investigators. Appx9. But the district court failed to recognize that importation is not inherently within (or outside) the safe harbor, and because Meril never actually used the Myval Devices at TCT, the only evidence connecting the importation to

recruiting investigators was Lad's declaration as to Meril's intent. Thus, the district court necessarily relied on the very intent evidence it deemed irrelevant.

The district court's several errors individually and collectively warrant reversal of its summary judgment Order and remand to allow a jury to resolve the genuine issues raised by the evidence.

ARGUMENT

I. STANDARD OF REVIEW AND MERIL'S BURDEN OF PROOF

The Federal Circuit reviews a grant of summary judgment *de novo*. *Ethicon Endo-Surgery, Inc. v. US Surgical Corp*., 149 F. 3d 1309. 1315 (Fed. Cir. 1998). Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *Id*., citing Fed. R. Civ. P. 56(c). "In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the party opposing the motion, with doubts resolved in favor of the opponent." *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1307 (Fed. Cir. 1998). Thus, at the summary judgment stage, the non-movant's version of any disputed issue of fact is presumed correct. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 456 (1992); *see also Union Pac. Corp. v. United States*, 5 F.3d 523, 525 (Fed. Cir. 1993) (in an appeal from a grant of summary judgment, all facts are construed in favor of non-movant). Thus, the district court is not permitted to weigh the evidence or make credibility determinations. *Tolan v. Cotton*, 572 U.S. 650, 656 (2014).

II. THE SECTION 271(e)(1) SAFE HARBOR DEFENSE

Section 271(e)(1) creates a limited safe harbor defense to a patent infringement claim, providing that "[i]t shall not be an act of infringement to . . . import into the United States a patented invention . . . solely for uses reasonably

related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . ." 35 U.S.C. § 271(e)(1) (emphasis added). The safe harbor defense applies to medical devices as well as drugs. *Eli Lily & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-74, 679 (1990). The safe harbor is an affirmative defense on which the accused infringer carries the burden of proof. *Ventrassist Pty Ltd. v. Heartware, Inc.* 377 F. Supp. 2d 1278, 1286 (S.D. Fla. 2005); see *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1272 (N.D. Cal. 1991).

The existence of some FDA-related activity at or near the time of the infringement is insufficient to sweep every act of infringement into the safe harbor. *Amgen I*, 565 F. 3d at 853. Rather, Meril has to prove that "each accused activity, was for uses reasonably related to submitting information to the FDA." *Amgen II*, 944 F.3d at 1339. The Supreme Court in *Merck* confirmed that "[e]ach of the accused activities must be evaluated separately to determine whether the exemption applies." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 200 (2005).

Consequently, in *Amgen I*, this Court reversed the ITC's grant of summary judgment under the safe harbor, which was based on a blanket assumption that all activities conducted pending regulatory approval were exempt. 565 F.3d at 852. This Court noted:

> To the extent that the Commission held all importation and all uses exempt while FDA approval was pending, the safe harbor statute does not so provide. The factual questions of the purposes of the post-BLA and other challenged activities were improperly summarily decided adversely to Amgen. On remand the Commission shall consider the exempt status of each study for which question has reasonably been raised.

Id. at 853.

The safe harbor defense is highly fact-dependent. *See Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1347 (Fed. Cir. 2007) ("The variety of experimental activity that may apply to any specific biologic or physiologic investigation reinforces the fact-dependency of the inquiry."); *Amgen II*, 944 F.3d at 1339-41 (upholding jury verdict that some acts of manufacturing were within the safe harbor and others infringing). Of course, such fact-intensive inquiries are not well suited to determination on summary judgment. For example, in *Isis Pharm., Inc. v. Santaris Pharma A/S Corp.*, No. 11-cv-2214, 2014 WL 794811 (S.D. Cal. Feb. 27, 2014), the court concluded that there was a triable issue of fact as to whether it was "objectively reasonable" for an alleged infringer to "believe that there was a decent prospect that the accused [infringing] activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question." *Id.* at *13, quoting *Merck*, 545 U.S. at 200-01. The court found that the defendant was not entitled to a judgment of non-infringement as a matter of law because the determination of what was

"reasonable" involved questions of fact. *Id.* And in *Chang v. Biosuccess Biotech Co.*, 76 F. Supp. 3d 1022 (C.D. Cal. 2014), the patent holder presented evidence that the accused infringer infringed by importing the accused pharmaceutical compound for reasons unrelated to seeking FDA approval, including adding indications for use and to generate information to support foreign patent applications. *Id.* at 1036-37. Like here, the patent owner submitted evidence of the infringer's public presentations regarding the domestic uses of the imported pharmaceutical product. *Id.* at 1037. The court found that, in view of this evidence, "the present record shows that there is a triable issue of fact" as to whether the importations were reasonably related to generating data for FDA submissions. *Id.*[4]

Here too, the record shows that there are triable issues of fact which, coupled with reasonable inferences in favor of the non-movant Edwards, preclude summary judgment.

[4] See also *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379, 1396-97 (N.D. Cal. 1987) (denying summary judgment based on evidence that sales and uses were not "solely for" meeting FDA requirements), *aff'd in part, rev'd in part*, 927 F.2d 1565 (Fed. Cir. 1991), *overruled on other grounds, Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009).

III. THE DISTRICT COURT ERRED IN GRANTING SUMMARY JUDGMENT IN FAVOR OF MERIL UNDER SECTION 271(e)(1)

A. THE DISTRICT COURT ERRONEOUSLY DISREGARDED CONTEMPORANEOUS EVIDENCE AND FAILED TO VIEW THE EVIDENCE IN THE LIGHT MOST FAVORABLE TO EDWARDS

The district court erroneously held that Meril's importation of Myval Devices to the TCT Conference was protected under the safe harbor statute "because Meril is a sponsor 'responsible for selecting qualified investigators and providing them with the necessary information to conduct clinical testing.'" Appx15. The Court simply accepted Meril's representation that it imported the Myval Devices to recruit clinical investigators at TCT, as alluded to in Meril's declarations. However, "at summary judgment, the judge must view the evidence in the light most favorable to the nonmoving party: if direct evidence produced by the moving party conflicts with direct evidence produced by the nonmoving party, the judge must assume the truth of the evidence set forth by the nonmoving party with respect to that fact." *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n,* 809 F.2d 626, 630-31 (9th Cir.1987); *see also Eastman Kodak*, 504 U.S. at 456 (at summary judgment, the non-movant's version of any disputed issue of fact is presumed correct); *Tolan*, 572 U.S. at 657-60 (vacating summary judgment where court improperly weighed evidence, failed to credit non-movant's contradictory evidence, and resolved disputed issues in favor of the moving party).

Here, there is strong contemporaneous evidence from the time of the importation from which a jury could reasonably conclude that Myval Devices were imported exclusively for use as commercial sales tools. For instance, Meril's marketing personnel drafted the two marketing pieces widely distributed by Meril before TCT inviting TCT participants to experience the Myval Devices "hands-on" at TCT. Appx616; Appx884-886; Appx670; Appx890-893; Appx746-748. Meril's marketing personnel drafted the first marketing piece planning the use of imported Myval Devices before Meril ever even communicated with the FDA about Myval. *Compare* Appx884-886, *with* Appx1015-1019. And notably, neither of these invitations to experience the Myval Devices at TCT mentioned clinical studies or Meril's purported desire to recruit clinical investigators. Appx884-886; Appx890-892; Appx746-748.

Significantly, the evidence most directly related to the imported Myval Devices instructed Meril's sales personnel on how to sell the valves at TCT: "Do not make any sales or offers for sale at the conference, or while in the United States or the [redacted]. **You can [redacted] for other countries**." Appx907-909 ("Instructions for TCT 2019 for Mval THV System)" (emphasis added). The same document instructs them: "Do not carry too many demo units" (*id.*), thus linking the imported Myval Devices to commercial sales activity.[5] Ignoring this evidence,

[5] The Instructions for Myval also stated: "If possible, refer discussions of pricing, delivery, and other commercial topics to representatives outside the US for

the district court found "transportation of the Myval Samples to the TCT Conference (**with no sales or offers for sale**) was an exempt act." Appx15 (emphasis added). The district court's finding that "no sales or offers for sale" occurred at TCT is clearly rebutted by Meril's Instructions to its TCT marketing team to "[redacted] for other countries." This finding alone, in view of the contrary evidence that the district court was required to accept, warrants reversal.

Significantly, Meril's "Instructions for TCT 2019 for Myval THV System," like its TCT invitation and email blast, never mention the FDA or the recruitment of clinical investigators. Appx907-909. Meril admitted that it planned and held only one meeting with prospective clinical investigators at TCT, yet Meril did not bring the imported Myval Devices to that meeting, and never even planned to. Appx618; *see* Appx705. In fact, Meril never showed the Myval Devices to a single clinical investigator at TCT. Appx373-374. Thus, the importation of the Myval Devices did not facilitate, and was not in any way related to, any recruitment activities of Meril.

The evidence also reveals that Meril's *marketing* personnel brought a simulator to demonstrate Myval Devices at TCT. Appx617, 625. However, Sanjeev Bhatt, Meril's principal recruiter for clinical trials, testified that he rarely uses sample devices and never used a simulator to recruit investigators. Appx669.

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the [redacted]." Appx909. Thus, not only did Meril instruct its sales personnel that they could [redacted] for other countries, they could even discuss U.S. sales, while referring the detailed terms to representatives outside the U.S. *Id.*

Nor did Meril's head of clinical research, Dr. Ashok Thakar, use sample devices, at medical conferences or otherwise. Appx705. Instead, Mr. Bhatt used PowerPoint presentations as his primary recruiting tool. Appx669.

From this evidence, a jury could reasonably conclude that Meril imported the Myval Devices solely to support commercial sales, rather than to recruit clinical investigators. The contemporaneous evidence directly contradicts the Meril declarations upon which the district court relied. Mr. Lad at best *implied* that Meril imported its devices to recruit clinical investigators, but he never expressly said so. He stated that TCT "provided a valuable opportunity for Meril to expand its network and identify potential clinical researchers for the FDA clinical trials . . .." Appx372. He testified that he flew the devices to San Francisco for TCT, but never connected that importation with "identifying potential clinical researchers." *Id*. The closest he came was stating, "Meril *considered* showing the Myval System to potential clinical investigators at the TCT conference," but decided not to do so because of technical difficulties with a simulator. Appx374 (emphasis added). And even the purported technical difficulties with the simulator are unsupported by contemporaneous evidence. Thus, Meril's declarations stopped shy of saying that the importation was indeed for use in recruiting clinical investigators. Yet the district court made that leap, and did so despite the contrary evidence discussed above.

Meril's argument that it was recruiting clinical investigators for its "Landmark Trial" raises further material issues of fact for a jury to decide. This Court and others have recognized that certain clinical studies are not protected, including post-approval studies "conducted for marketing purposes, with the objective of trying to distinguish" the device at issue from a competitive product. *Amgen I*, 565 F.3d at 852-53. Further, otherwise infringing acts undertaken in connection with foreign clinical investigations are not within the statute. *NeoRx*, 877 F. Supp.at 208-209 (denying summary judgment in part because "the lack of a clear indication that [foreign clinical] work was submitted, or to be submitted, to the FDA argues in favor of a determination that his studies were not reasonably related to FDA submission").

Here, the evidence shows that Meril's Landmark Trial was and is a commercially motivated comparative study to be conducted exclusively outside the United States. *See* Appx912; Appx915-916; Appx926, 946-958. All contemporaneous documents up to the time of Meril's importation show that the Landmark Trial was wholly unrelated to any FDA approval. The evidence contradicts Meril's implication that its importation was related to plans to conduct "clinical studies in the United States." Appx372-374. At least seven contemporaneous documents state that, around the time of the importation and during TCT, Meril had no plans for domestic investigation sites for the Landmark

Trial. Appx590 (citing Appx842; Appx912; Appx915-916; Appx926, 946-958; Appx1013; Appx1015-1016; Appx1021-1022).

From this evidence, a jury could reasonably conclude that the Landmark Trial is entirely unrelated to generating clinical data for FDA submissions. Indeed, this Court has recognized that clinical trials are sometimes performed for purposes that are not protected under the safe harbor, such as a marketing study to distinguish a product from its competitors. *Amgen I*, 565 F.3d at 852-53 (denying summary determination of safe harbor defense and requiring factual inquiry into purpose of clinical studies); *see also Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1070 (Fed. Cir. 2011) (safe harbor does not apply to the studies that were not *mandated* by the FDA and were not for the purpose of "expedit[ing] development of information for regulatory approval"); *Amgen II*, 944 F.3d at 1340 (sustaining jury verdict rejecting defense where expert had "testified that [the accused infringer] was not **required** to manufacture additional batches after it made its 2012 batches" for FDA approval) (emphasis added).

Where the evidence permits a jury to conclude that the alleged infringing conduct is solely for commercial uses, the infringing conduct does not fall within the safe harbor. For instance, in *Amgen II*, Amgen sued Hospira for infringing Amgen's patented process for making a drug substance. *Id.* at 1332-33. Hospira manufactured twenty-one batches of the substance, and the jury found that the manufacturing of seven batches was protected under the safe harbor, while the

manufacturing of the other fourteen was not. Two of the protected batches were used for qualifying Hospira's manufacturing process and some alternate equipment, and five were used for a mandatory pre-approval inspection by the FDA. *Id.* at 1339. The jury found that all other batches were not exempted by the safe harbor in part because evidence showed they were manufactured to build commercial inventory. Hospira argued that its commercial intent was irrelevant, but the court disagreed, stating that, while Hospira's "decision to manufacture its . . . 'commercial inventory' was not dispositive of the Safe Harbor defense, . . . this evidence was probative of whether Hospira's use of Amgen's patented process was reasonably related to seeking FDA approval." *Id.* at 1340.

In granting summary judgment here, the district court dismissed the extensive evidence that Meril imported the Myval Devices for commercial uses. Rather, it erroneously found, based exclusively on Meril's litigation declarations, that the importation "was reasonably related to the submission of information to the FDA." Appx10. The district court appeared to reason based on this Court's *Abtox* decision that, once an otherwise infringing act is determined to be reasonably related to obtaining FDA approval, Meril's intent or alternative uses for the importation were irrelevant. Appx14-16, 16 n.7 (citing *Abtox, Inc. v. Exitron Corp.* 122 F.3d 1019, 1330 (Fed. Cir. 1997)). But in making the initial determination that the importation was reasonably related to obtaining FDA approval, the district court failed to draw all reasonable inferences in favor of

Edwards, the non-moving party. Indeed, the district court failed even to consider that evidence because it relegated it to "alternative uses," when, in fact, all the contemporaneous evidence supports that selling the Myval Devices was the only use for which Meril imported them. Moreover, the district court ignored the evidence of Meril's commercial intent, even though this Court had determined that such evidence is at least "probative of whether [the alleged infringement] was reasonably related to seeking FDA approval." *Amgen II*, 944 F.3d at 1340.

The district court thus failed to properly acknowledge key evidence offered by Edwards, and hence "the court below neglected to adhere to the fundamental principle that at the summary judgment stage, reasonable inferences should be drawn in favor of the nonmoving party." *Tolan*, 572 U.S. at 660.

B. THE DISTRICT COURT RELIED INSTEAD ON DECLARATIONS FROM MERIL EMPLOYEES WHO LACKED PERSONAL KNOWLEDGE

In considering Meril's motion for summary judgment, the district court was required to view any inferences reasonably drawn from the evidence in the light most favorable to Edwards. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986). It failed to do so, and instead, it appears the Court principally relied on self-serving declarations from Meril employees who often lacked personal knowledge of the facts declared. Specifically, the district court erred by crediting Meril's uncorroborated declaration testimony as the sole basis for finding that Meril's importation "was reasonably related to the submission of

information to the FDA," and thus, "Meril's transportation of non-commercial Myval Samples to the TCT Conference is exempt under the safe harbor." Appx10 (citing **only** Appx372-374 (Lad Decl. ¶¶ 13-15, 17)).

As a threshold matter, the district court's binary statement that the Myval Samples were "non-commercial," apparently based on the fact that Myval Devices were not approved for sale in the United States, ignores the undisputed evidence that they were approved for sale in Europe, and that the TCT Conference was a huge international marketing opportunity. *See supra* Statement of Facts §§ I-II. The district court also appeared to overlook at least the following bases for a reasonable inference that Meril's importation was to support its sales efforts entirely unrelated to any clinical recruiting or FDA-related activities:

(1) the fact that Meril's marketing personnel drafted Meril's promotional materials for TCT, inviting physicians to experience the Myval Devices "hands-on" at TCT, and the absence of any reference to clinical recruitment in these materials, even though similar invitations for other trade shows specifically mention Landmark Trial investigator meetings (*compare* Appx616, Appx884-886, Appx670, Appx890-892, *and* Appx746-748, *with* Appx964-965 (e-blast sent to London Valves conference attendees advertising "9 Landmark Trial investigator meetings"));

(2) the explicit permission to "[redacted] for other countries" and the absence of any reference to recruiting clinical investigators for FDA submissions

in the contemporaneous Instructions to all Meril employees attending TCT (Appx907-909);

(3) the evidence that Meril never even planned to bring the imported Myval Devices to its only meeting with potential clinical investigators at TCT (Appx618; *see* Appx705);

(4) Meril's principal clinical recruiter's testimony that he used PowerPoint presentations rather than actual demonstration valves to recruit investigators (Appx669);

(5) the fact that Meril never used or demonstrated the imported devices at TCT at all (Appx373-374);

(6) the fact that the imported devices were physically transported by Meril's employee Nilay Lad, whose job functions are entirely unrelated to clinical trials or clinical recruiting (Appx370, 372-374; Appx612-613);

(7) the fact that the Landmark Trial was a post-EU-approval trial to establish market credibility against competing devices, rather than a single-arm trial typical for regulatory approval (Appx370; Appx588-589; Appx912; Appx591; Appx915; Appx923, 946, 953; Appx969, 996-997; Appx657);

(8) the fact that Meril's only contemporaneous written references to the Landmark Trial did not involve any U.S. sites that Meril knew would be required for FDA submissions (Appx1021-1022; Appx1015-1016; Appx946, 953; Appx677; Appx716);

(9) the fact that Meril first contacted the FDA *after* it had already decided to import its Devices to TCT, *after* the same devices had been seized for alleged patent infringement at a prior trade show in France, and *after* Meril [redacted] about its plan to import the devices to TCT (Appx884-886; Appx616; Appx1015-1019; Appx547; Appx609-613; Appx869-873); and

(10) the fact that Meril routinely ignored its own FDA consultant and FDA guidance regarding the voluntary presubmission and study design, signaling it had no genuine plans to convert the Landmark Trial to one that could be used for FDA approval (Appx1036; Appx1047; Appx1049-1050).[6]

All of the foregoing support the inevitable conclusion that factual issues abound as to two major factual issues. First, whether Meril imported the Myval Devices to recruit clinical investigators, given the extensive contemporaneous evidence that it planned to use the imported Myval Devices solely as commercial sales tools. In contrast, no documentary evidence connected the imported Myval Devices to "recruiting clinical investigators." Second, there was a triable issue of fact as to whether it was "objectively reasonable" for Meril to "believe that there was a decent prospect that the [importation] would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the

[6] In all public presentations about the Landmark Trial, both before and after importing Myval Devices for TCT, Meril presented it as an entirely OUS trial. Appx588-589; Appx910, Appx912; Appx923, Appx946, Appx953; Appx969, Appx996-997; *see* https://clinicaltrials.gov/ct2/show/NCT04275726?term=myval&draw=2&rank=2.

processes by which the FDA would decide whether to approve the product in question." *Isis Pharm.*, 2014 WL 794811 at *13 (quoting *Merck*, 545 U.S. at 200-01) (emphasis added).

Here, the evidence supports a finding that it was not objectively reasonable for Meril to believe that importing devices, allegedly to recruit clinical investigators for a post-EU-approval OUS trial, would contribute "relatively directly" to generating relevant information for the FDA to approve the Myval Devices. Indeed, Meril knew that the FDA would require a trial with mostly U.S. subjects and did not believe that sample devices were useful recruiting tools in any event. The district court also failed to consider the preliminary and voluntary nature of Meril's FDA presubmissions. *See* Appx9. Moreover, to the extent the district court held that Meril believed that importing the Myval Devices would contribute relatively directly to FDA approval and that its belief was "objectively reasonable," it did so solely based on the declaration of Mr. Lad. But Mr. Lad had no experience in that area, and his declaration was completely lacking in establishing a foundation for his purported knowledge. Appx612-613; Appx370.

It is well-settled that a court should not grant summary judgment based solely on an uncorroborated, self-serving declaration (particularly in light of contradicting contemporary evidence), just as it cannot deny summary judgment based solely on an uncorroborated, self-serving declaration. *Villiarimo v. Aloha Island Air, Inc.*, 281 F.3d 1054, 1059 n.5, 1061 (9th Cir. 2002) (holding that the

district court properly disregarded a declaration that included facts beyond the declarant's personal knowledge and did not indicate how she knew the facts to be true) (*citing Kennedy v. Applause, Inc.*, 90 F.3d 1477, 1481 (9th Cir. 1996)); *Hopkins v. Andaya*, 958 F.2d 881, 888 (9th Cir. 1992) (a single contemporaneous medical record was sufficient to overturn summary judgment in favor of defendant, which the district court granted based on the defendant's self-serving and uncorroborated deposition testimony).

Lad's declaration, insofar as it purports to support a safe harbor defense, also concerns matters on which he clearly lacks personal knowledge. His job responsibilities in August and September of 2019 had nothing to do with regulatory submissions, recruiting clinical investigators, selling Myval Devices, or transporting devices to trade shows. Appx612-614. Lad lacks any experience related to FDA submissions or clinical trials, and his only role with respect to the Myval Devices was managing litigation. *Id.* Yet his declaration purports to explain the FDA approval process for heart valves and its requirements with respect to OUS and domestic clinical trials. Appx370-373. And the district court accepted that explanation despite contrary evidence that the Landmark Trial was unrelated to FDA submissions. *See* Appx9.

Further, Lad was not involved in Meril's announcements concerning its intention to bring Myval Devices to TCT for hands-on demonstrations. Appx616,

619-620.[7] Indeed, Lad's only involvement with Myval was managing litigation. Appx612-613.

Accordingly, the district court erroneously credited the Lad Declaration, failed to acknowledge the contradicting contemporaneous evidence, and neglected to draw reasonable inferences from that evidence in favor of Edwards. These errors warrant reversal of the district court's grant of summary judgment.

C. THE DISTRICT COURT PURPORTED TO APPLY AN OBJECTIVE STANDARD YET RELIED ON MERIL'S ALLEGED SUBJECTIVE INTENT FOR THE IMPORTATION

The district court purported to apply an objective standard to determine whether Meril's importation was solely for uses reasonably related to FDA submissions, noting that "consistent with the language of the statute, the safe harbor inquiry focuses on acts or uses, and not on purposes, intent or motive." Appx7. As acknowledged by the district court, the safe harbor statute delineates several potentially infringing acts – i.e., making, using, offering to sell, selling, or importing – that might fall within the safe harbor if certain conditions are met. Appx8. However, in describing those conditions the statute separately refers to "uses" of the accused devices. 35 U.S.C. § 271(e)(1) ("It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import

[7] Lad testified that he and Mr. Bhatt did not decide to import Myval Devices until a few days before TCT, but Meril's TCT invitations and email blast show that the decision was made much earlier. Appx602-603; Appx882; Appx884-886; Appx890-893. This is yet another factual dispute that the district court overlooked.

into the United States a patented invention . . . solely for **uses** reasonably related to the development and submission of information under Federal law . . .") (emphasis added). This distinction is significant because the infringing acts, such as importation or manufacture, are not inherently related, nor unrelated, to submitting information to the FDA. *See, e.g.*, *Amgen II*, 944 F.3d at 1340 (finding some manufacturing activities protected and others infringing); *Chang*, 76 F. Supp. 3d at 1035 (holding that defendant had "not presented evidence sufficient to establish that this importation of TPA was for the sole purpose of developing information to submit to the FDA"). However, the dichotomy in the statutory language has led one district court to stress that "the availability of the exemption turns on actual uses." *Intermedics*, 775 F. Supp. at 1275. "[Courts are] to focus on conduct ('uses') that actually has occurred (as opposed to uses to which a party might put its product in the future)." *Id.* at 1278 (emphasis added). "[W]e simply ask: are these actual uses 'solely . . . reasonably related to the development and submission of information' to the FDA." *Id.* at 1280. This Court has also held that "[t]he statute . . . does not look to the underlying purposes or attendant consequences of the activity . . . as long as the **use** is reasonably related to FDA approval." *Abtox*, 122 F.3d at 1030 (emphasis added).

Here, the district court appeared to overlook the statute's distinction between the potentially infringing conduct (make, use, offer to sell, sell, import), on the one hand, and the uses that may bring that conduct within the safe harbor (uses

reasonably related to an FDA submission), on the other hand. It concluded that "importation by itself (without actual use) can fall within the safe harbor." Appx8. The district court quoted *Abtox* in further holding that "'[Meril's] intent or alternative uses are irrelevant to its qualification to invoke the section 271(e)(1) shield.'" *Abtox*, 122 F.3d at 1030. Accordingly, Defendants' underlying purposes are not relevant to the safe harbor inquiry." Appx15. This holding misreads *Abtox* and ignores *Amgen II*, which confirmed that evidence of commercial intent is at least probative of whether use of the patented process was reasonably related to seeking FDA approval. 944 F.3d at 1340. Indeed, because there was no actual post-importation use, evidence of Meril's intent appears to be the **only** probative evidence on applicability of the safe harbor.

The district court ignored the critical part of this Court's holding, namely that "**As long as the activity is reasonably related to obtaining FDA approval**, [the accused infringer's] intent or alternative uses are irrelevant to its qualification to invoke the section 271(e)(1) shield." *See* Appx15 (quoting only a portion of *Abtox*, 122 F.3d at 1030 (emphasis added)). Thus, before Meril's intent and alternative uses can be deemed irrelevant, a determination must be made that "the activity is reasonably related to obtaining FDA approval." Given there was no actual use after importation, the only activity to be examined is the importation itself, and the only evidence connecting the importation to obtaining FDA approval is evidence of Meril's subjective intent. However, that evidence (principally

Meril's self-serving declarations) is disputed by other evidence of Meril's solely commercial intent. The district court thus erred in deeming Meril's intent irrelevant in the absence of evidence of a protected use.

Regardless of whether the safe harbor statute requires an actual use in addition to the infringing act, the district court erred in granting summary judgment. To the extent an actual use is required, there was no actual use beyond mere importation. To the extent no actual use is required, the only evidence that connects Meril's importation to a use that falls within the safe harbor is the disputed evidence of Meril's subjective intent. That extensive evidence creates genuine issues of fact, particularly when all reasonable inferences are drawn in favor of Edwards.

It is undisputed that Meril never actually used the imported Myval Devices at TCT. Appx373-374; Appx618. Meril never showed them to anyone and never removed them from the bag used to transport them. *Id*. Accordingly, to the extent the safe harbor statute requires an "actual use," there was none. Indeed, if the statute requires actual use, and intent is irrelevant, the district court erred because it relied solely on evidence of Meril's alleged intent to use the Myval Devices to recruit investigators. And again, importation itself cannot be inherently exempt under the safe harbor because some "generic" acts of infringement (manufacturing, importation, etc.) are covered, and some are not. *Amgen II*, 944 F.3d at 1340 (manufacturing); *Chang*, 76 F. Supp. 3d at 1036 (importation).

On the other hand, if Meril's intended use for the imported devices is relevant (including because there was no actual use), a wealth of contemporaneous evidence contradicts any implied finding by the district court that Meril intended to import the Myval Devices for recruiting clinical investigators to develop FDA-related data. A fact-finder considering that evidence could reasonably conclude that Meril's purpose in importing its valves to TCT was solely commercial in nature. Again, it was Meril's marketing personnel, not its clinical personnel, who invited TCT attendees to experience "hands-on" Myval sessions at TCT. Appx882; Appx884-886; Appx890-893; Appx616, 619-620; Appx670. These invitations never mentioned clinical investigators or clinical trials. Appx882; Appx884-886; Appx890-893. Meril admitted it never even planned to bring its devices to its only meeting with potential clinical investigators at TCT. Appx618. And its principal recruiter for clinical trials testified that he uses PowerPoint presentations rather than sample devices for recruiting purposes. Appx669. Thus, the evidence at least supports, if not requires, the inference that Meril's purpose for importing the Myval Devices to TCT was solely for use as a commercial sales tool, and not for any use reasonably related to generating information for the FDA.

Finally, the district court also erred in holding that "demonstrations at medical conferences are covered by the Section 271(e)(1) safe harbor," regardless of actual use or intended use. Appx8-9. In the cases cited by the district court, it was undisputed that at least one purpose of the accused infringer's actual use was

recruitment of clinical investigators for an FDA-sanctioned clinical trial. *See Telectronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1522-23 (Fed. Cir. 1992) (undisputed that the defendant also demonstrated the device to clinical investigators); *see also Intermedics*, 775 F. Supp. at 1287 (patent owner did not dispute that defendant's actual demonstrations were, in part, reasonably related to obtaining FDA approval). Moreover, the defendants in both cases already had IDEs, so unlike Meril they were actually permitted to conduct clinical trials in the United States. *Telectronics*, 982 F.2d at 1521; *Intermedics*, 775 F. Supp. at 1276.

Here, by contrast: (a) there was no actual demonstration of the Myval Devices to clinical investigators, or any other use, (b) Meril was and still is nowhere near obtaining the IDE approval required for domestic clinical trials, and (c) it is very much disputed based on the contemporaneous evidence that recruiting clinical investigators for FDA approval was Meril's purpose for importing its devices. Moreover, the evidence supports an inference that Meril's sole purpose for importing Myval Devices was to support its commercial sales efforts, and the importation was wholly unrelated to recruiting clinical investigators and wholly unrelated to any FDA submission.

In sum, the district court erred in granting safe harbor protection on summary judgment to Meril's infringing act of importing the Myval Devices. The district court acknowledged that Meril did not use the Myval Devices once imported, yet erroneously found that Meril's actual use reasonably related to FDA

submissions. In doing so, it erroneously relied on Meril's declarants' stated intent for the importation—the recruitment of clinical investigators for a non-existent FDA trial. But Meril's own documents and admissions would permit a reasonable fact-finder to conclude that Meril imported the Myval Devices for its marketing employees to use as commercial sales tools at TCT. Thus, the grant of summary judgment cannot stand.

CONCLUSION AND RELIEF SOUGHT

Edwards respectfully submits that the Court should reverse the Judgment and the district court's Order granting summary judgment, and direct the district court that Meril's safe harbor defense should be decided at trial, if trial of Edwards' patent infringement claims is otherwise appropriate.

DATED: September 22, 2022 By: */s/ Christy G. Lea*
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ADDENDUM

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

EDWARDS LIFESCIENCES CORPORATION, et al.,

Plaintiffs,

v.

MERIL LIFE SCIENCES PVT. LTD., et al.,

Defendants.

Case No. 19-cv-06593-HSG

ORDER GRANTING MOTION FOR SUMMARY JUDGMENT AND GRANTING IN PART AND DENYING IN PART MOTIONS TO SEAL

Re: Dkt. No. 67

Pending before the Court is Defendants Meril Life Sciences PVT. LTD ("Meril Life Sciences") and Meril, Inc. (collectively, "Defendants," or "Meril") Motion for Summary Judgment, for which briefing is complete. Dkt. Nos. 67 ("Mot."), 82 ("Opp."), and 90 ("Reply"). The parties have also filed administrative motions to seal ("Motions to Seal") portions of their briefs and exhibits related to the Motion. *See* Dkt. Nos. 66, 81, 87, 89. On September 24, 2020, the Court held a hearing on the Motion. Dkt. No. 96. For the reasons below, the Court **GRANTS** Defendants' Motion for Summary Judgment, and **GRANTS IN PART** and **DENIES IN PART** the Motions to Seal.

I. BACKGROUND[1]

Meril Life Sciences is an India-based, global medical device company that was founded in 2007. Declaration of Nilay Lad (Dkt. No. 67-3, "Lad Decl.") ¶ 2. Meril, Inc. is a wholly owned subsidiary of Meril Life Sciences. *Id.* Meril created a "Myval" branded transcatheter heart valve, which is designed to be used with a "Navigator" delivery system (collectively, the "Myval System"). *Id.* ¶ 3; Declaration of Sanjeev Bhatt (Dkt. No. 67-1, "Bhatt Decl.") ¶ 3. Edwards

[1] The following facts are undisputed unless otherwise noted.

Lifesciences Corporation ("Plaintiff" or "Edwards") is a supplier of medical devices for the treatment of heart disease, including artificial heart valves. Among its best-known products are its "SAPIEN®" transcatheter prosthetic heart valves.

The Myval System is intended to treat severe symptomatic native aortic valve stenosis, a condition where the aortic valve narrows and restricts normal blood flow. *Id.* In 2016, Meril's experimentation with the Myval System led up to a cadaver procedure "to determine the feasibility of implanting the Myval transcatheter heart valve into human subjects" at the University of Washington ("UW") in January 2017. Bhatt Decl. ¶ 4. In January 2017, Meril shipped six samples of the Myval System to UW to conduct these pre-clinical investigations on cadavers, and to determine whether the Myval transcatheter heart valve could be safely implanted in future clinical studies. *Id.* Members of the UW team successfully implanted the Myval transcatheter heart valve in cadavers, which enabled Meril to plan its clinical studies with human subjects. *Id.*[2]

Meril first began conducting clinical trials for its Myval System in India in June 2017, and received approval from the Drug Controller General of India on October 31, 2018. Lad Decl. ¶ 4. In April 2019, the Myval System was granted the CE marking, which certifies its conformance to health and safety standards for products sold within the European Economic Area. *Id.* In the United States, the Myval System is considered a "Class III" medical device subject to strict regulatory standards. *Id.* ¶ 5; 21 U.S.C. § 360c(a)(1)(C) (classifying a Class III device as "for use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health"). Therefore, Meril may not lawfully market or sell the Myval System in the United States without first receiving mandatory premarket approval from the United States Food and Drug Administration ("FDA"). Lad Decl. ¶ 5; 21 U.S.C. § 360c; 21 C.F.R. §

[2] Around this time, Meril also began planning a preclinical animal study for Myval with the CRF Skirball Center for Innovation in New York ("Skirball Study"). Dkt. No. 87-6 ("Stephens Decl.") Ex. 13 at 4:23-28. The Skirball Study was to investigate the feasibility of implanting the Myval System into humans, and whether Meril could do so safely in clinical studies. *Id.* In 2016, Meril sent three samples of the Myval transcatheter heart valve ("THV") and the Myval System for the Skirball Study, and six Myval Samples to UW. Bhatt Decl. ¶ 4; Stephens Decl. Ex. 13 at 4:23-28. The Skirball Study occurred on January 27, 2017, and the results were documented in a written report. Dkt. No. 90-1 ("Mayer Reply Decl.") Ex. 15.

812.20; 21 C.F.R. § 812.42.

To receive premarket approval from the FDA, Meril must first apply for and obtain an investigational device exemption ("IDE") from the FDA, identify clinical investigators to implant the device in human subjects, collect data from those subjects, and then submit the data to the FDA. Lad Decl. ¶ 5; Bhatt Dec. ¶ 5. IDE applications require sponsors to describe all preclinical testing and include reports of prior investigations. Dkt. No. 67-15, Declaration of Melanie Mayer ("Mayer Decl."), Ex. 4 at MERIL00000542.

The premarket approval process can be lengthy and difficult to navigate, and Meril began preparations ahead of its planned IDE application. First, Meril began preparing for a pre-submission to the FDA, which allows device manufacturers to request formal regulatory feedback on the device before officially engaging in the premarket approval process. Lad Decl. ¶¶ 6-7; Mayer Decl., Ex. 1 at MERIL00000404. The pre-submission program allows device makers like Meril to obtain guidance from the FDA about its premarket submissions, which in turn improves the quality of submissions and shortens total review times. Lad Decl. ¶ 6; Mayer Decl., Ex. 1 at MERIL00000404.

In May 2019, Meril imported a number of Myval System devices to a large conference in France called EuroPCR. Dkt. No. 84-1, Ex. A ("Lad Depo.") at 76-78. Edwards appears to have anticipated this importation, and filed a proceeding in France authorizing the seizure of the Myval Devices based on the alleged infringement of Edwards' European patents. *Id.* A brochure was seized that included an updated new slide on Meril's Global Clinical Program, with the first mention of a "Landmark Trial." *See* Stephens Decl. ¶ 82; Ex. 34. This "Landmark Trial" was to be a three-arm trial comparing the Myval System with the market leading devices in Europe, Edwards' SAPIEN valves and Medtronic's CoreValve Evolut valves. Dkt. No. 84-2, Ex. B ("Bhatt Depo.") at 50-51.

In late August 2019, Meril contacted the FDA to inquire about the Landmark Trial and the preliminary requirements for filing a pre-submission. Lad Decl. ¶ 7, Exs. A, B. In early September 2019, Meril also contacted CardioMed LLC, a medical device consulting company that provides regulatory and clinical trial consulting services, including for premarket approval

submissions, and sought its help in preparing a pre-submission filing to the FDA for the Myval System. *Id.* ¶ 8, Ex. C.

Meril then sought out potential clinical researchers at the 2019 Transcatheter Cardiovascular Therapeutics Conference in San Francisco ("TCT Conference")—an annual scientific symposium hosted by the Cardiovascular Research Foundation ("CRF") featuring the latest developments in interventional cardiovascular medicine, and attended by leading researchers and clinicians. *Id.* ¶ 10; Mayer Decl., Ex. 3. In advance of the TCT Conference, Meril provided CRF a digital flyer containing information about Meril's booth and its agenda at the conference. *Id.* ¶ 11. CRF then distributed this flyer to individuals and organizations who had subscribed to receive email updates about the TCT Conference. *Id.* It is undisputed, however, that the Myval System was never shown to anyone after it was imported into the United States. *Id.* ¶ 17; Lad Depo. at 95-96.

Nilay Lad, a Meril employee, traveled to San Francisco on September 24, 2019 to attend the TCT Conference. Lad Decl. ¶ 13. He carried with him two Myval THV's, Myval THV's with rubber leaflets, and two Navigator delivery systems (collectively, "Myval Samples") on his flight into San Francisco International Airport. *Id.* The Myval Samples were contained in a bag, and accompanied by a written declaration stating:

> This is to inform you that the demo samples carried by Mr. Nilay Lad is for the demonstration purpose only.
>
> It is consist [sic] of Demo samples of Medical devices. They have no commercial value & hence it is not used for any sales purpose. The demo samples are NON-STERILE. NOT FOR HUMAN USE. NOT FOR SALE. NOT APPROVED FOR SALE IN UNITED STATES. FOR DEMO PURPOSE ONLY AT TCT 2019, SAN FRANCISCO.

Id., Ex. F.

Meril had a booth at the TCT Conference from September 26 to September 28, and provided information on its cardiovascular systems, including the Myval System, in the form of visual displays and presentations to attending physicians. *Id.* ¶ 14, Exs. G-H. For the Myval System, Meril exhibited patient case studies, information on the Myval System and its use in a clinical trial, and information about the placement of the Myval System in patients. *Id.* Meril stated to conference attendees that the Myval System was not yet approved by the FDA, and that it

was not available for sale in the U.S. *Id*. Meril also discussed the details of the Myval System with several U.S. doctors to identify potential clinicians for its premarket approval application. *Id.* ¶ 15.

Meril considered showing the physical Myval System in conjunction with a simulation system that would provide potential clinicians with a hands-on opportunity to interact with the physical devices. However, because of alleged technical difficulties with the simulation system, Meril did not show the physical Myval samples at the TCT Conference. *Id.* ¶ 17. Meril also did not offer for sale or sell the Myval System to any non-U.S. customers at the TCT Conference. *Id.* ¶ 15. Because Meril did not exhibit the physical Myval Samples, Mr. Lad maintained the samples overnight in a bag in a storage room at the TCT Conference. The samples were never taken out of the bag or displayed to any conference attendees. *Id.*

On September 28, Mr. Lad gave the Myval Samples to another Meril employee, Sanjeev Bhatt, to take to Europe on September 30. *Id.*; Bhatt Decl. ¶ 6. For a short period of time after Meril attended the TCT Conference, Meril's LinkedIn page stated that 2,000 people visited its booth at the TCT Conference and that Meril had exhibited the Myval System at its booth. Lad Decl. ¶ 18. Meril later removed the LinkedIn post. *Id.*

II. LEGAL STANDARD

Summary judgment is proper when a "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" if it "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). And a dispute is "genuine" if there is evidence in the record sufficient for a reasonable trier of fact to decide in favor of the nonmoving party. *Id.* But in deciding if a dispute is genuine, the court must view the inferences reasonably drawn from the materials in the record in the light most favorable to the nonmoving party, *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986), and "may not weigh the evidence or make credibility determinations," *Freeman v. Arpaio*, 125 F.3d 732, 735 (9th Cir. 1997), *overruled on other grounds by Shakur v. Schriro*, 514 F.3d 878, 884–85 (9th Cir. 2008). If a court finds that there is no genuine dispute of material fact as to only a single claim or defense or as to

part of a claim or defense, it may enter partial summary judgment. Fed. R. Civ. P. 56(a).

III. DISCUSSION

Defendants contend that they did not infringe Plaintiff's patents because (1) Meril did not use or exhibit Myval samples during the TCT Conference, and (2) Meril's transportation of its Myval-branded transcatheter heart valve system to UW in 2017 and to the TCT Conference was reasonably related to its premarket submissions to the FDA, and is thus protected by the safe harbor exemption under 35 U.S.C. § 271(e)(1).

A. Safe Harbor Application

Congress enacted 35 U.S.C. § 271(e)(1) to address issues created by the legal requirements for pre-market FDA approval of drugs and medical devices, particularly those involving patented inventions. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990). One of these issues was that third parties wishing to sell the patented product upon patent expiration had to engage in a lengthy FDA approval process, essentially creating a *de facto* extension of the patent while FDA approval was pending. *Id.* at 670.

To address this problem, Congress enacted the safe harbor of Section 271(e)(1), which provides that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." Put differently, Section 271(e)(1) allows competitors, before the expiration of a patent, to engage in otherwise infringing activities if the use is "reasonably related to" obtaining regulatory approval. Courts routinely decide the applicability of the safe harbor at the summary judgment stage. *See, e.g.*, *Genentech, Inc. v. Insmed Inc.*, 436 F. Supp. 2d 1080, 1095 (N.D. Cal. 2006); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1059 (Fed. Cir. 2011).

Section 271(e)(1) undisputedly can apply to medical devices like the Myval System. *Eli Lilly*, 496 U.S. at 661. Section 271(e)(1) "provides a wide berth for the use of patented [inventions] in activities related to the federal regulatory process." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005); *see also Med. Diagnostic Labs., L.L.C. v.*

Protagonist Therapeutics, Inc., 298 F. Supp. 3d 1241, 1247 (N.D. Cal. 2018). The Supreme Court has explained that "[Section] 271(e)(1)'s exemption from infringement extends to *all* uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA [Federal Food, Drug, and Cosmetic Act]," which "necessarily includes preclinical studies." *Merck KGaA*, 545 U.S. at 202 (emphasis in original). The safe harbor also applies regardless of the phase of research, and even if the information is never ultimately submitted to the FDA as part of an approval application. *Id.* at 202, 205 ("There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included."); *see also Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1027 (Fed. Cir. 1997) (finding the safe harbor applicable where, "[a]t the time of this litigation, [defendant] had neither filed an application for approval with the FDA nor otherwise marketed the device").

As the Supreme Court explained, an activity is "reasonably related" to federal regulatory activities if an accused manufacturer has a reasonable basis for believing that a device may work to achieve a particular result, and uses the device in research that, if successful, would be appropriate to include in a submission to the FDA. *Merck KGaA*, 545 U.S. at 207; *see also Intermedics, Inc. v. Ventritex, Inc*., 775 F. Supp. 1269, 1280 (N.D. Cal. 1991) ("*Intermedics I*") (proper inquiry is whether "it [would] have been reasonable, objectively, for a party in defendant's situation to believe that there was a decent prospect that the 'use' in question would contribute . . . to the generation of [] kinds of information … likely to be relevant in the processes by which the FDA would decide whether to approve the product").

Similarly, consistent with the language of the statute, the safe harbor inquiry focuses on acts or uses, and not on purposes, intent or motive. *See* 35 U.S.C. § 271(e)(1) (extending protection to "uses reasonably related"). The Federal Circuit has explained that "[t]he breadth of the exemption [under Section 271(e)(1)] extends even to activities the 'actual purpose' of which may be 'promot[ional]' rather than regulatory, at least where those activities are 'consistent with the collection of data necessary for filing an application with the [FDA].'" *Momenta Pharm., Inc. v. Teva Pharm. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015) (citing *Abtox*, 122 F.3d at 1027).

Plaintiff contends that the safe harbor requires an "actual use." Opp. at 16. However, as noted, the safe harbor provides that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1). The statute lists each of the possibly infringing acts (making, using, offering to sell, selling, and importing) separately, making clear that importation by itself (without actual use) can fall within the safe harbor. The clause "solely for uses reasonably related to the development and submission of information" to the FDA also does not require an "actual use." As the Federal Circuit has explained, the safe harbor applies "[a]s long as the [allegedly infringing] activity [*e.g.*, making, using, selling, offering for sale, and importing] is reasonably related to obtaining FDA approval." *Abtox*, 122 F. 3d at 1030.

Here, Defendants contend that there can be no genuine dispute that all the accused activities were directed at furthering Meril's clinical investigation of its Myval System for future FDA approval and thus fall squarely within the scope of the safe harbor. Plaintiff alleges two acts of infringement: (1) Meril "imported" the Myval System into the United States in 2017 so that UW could conduct a pre-clinical cadaver study (Dkt. No. 51 ¶ 40); and (2) Meril "imported" and "exhibited" at least one Myval System at the 2019 TCT Conference. *Id.* ¶ 39.

i. 2019 TCT Conference

Meril contends that the shipment of samples to the TCT Conference falls within the safe harbor because Meril did not exhibit the Myval System during the TCT Conference. Lad Dec. ¶ 17. Meril states that although it transported a number of Myval Samples to the TCT Conference planning to demonstrate the physical device to potential clinical researchers, it had technical difficulties with the simulation system, with the result that the Myval Samples remained stored away during the time they were in San Francisco and were not shown to any conference attendees. *Id.* Accordingly, Meril contends that there can be no infringement.

According to the Federal Circuit, demonstrations at medical conferences are covered by the Section 271(e)(1) safe harbor. *Intermedics, Inc. v. Ventritex Co.*, No. 92-1076, 1993 WL 87405, at *3 (Fed. Cir. Feb. 22, 1993) ("*Intermedics II*") ("Assuming that these nonsale

demonstrations at medical conferences constitute an infringing use, we have held they are an exempt use that is reasonably related to procuring FDA approval of the device."); *Chartex Intern. PLC v. M.D. Personal Products Corp.*, 5 F.3d 1505, 1993 WL 306169, at *4 (Fed. Cir. 1993) (affirming summary judgment of non-infringement because exhibition of device at trade show was either a non-infringing act under 35 U.S.C. § 271(a) or exempt under the Section 271(e)(1) safe harbor). And transporting a device to a medical conference is a necessary and predicate act for displaying the device, such that the transportation of an accused device into a country for display at a medical conference is also exempt under the safe harbor. *See Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1564 (Fed. Cir. 1996) (importing accused product into the U.S. "for use in clinical trials in support of . . . application for FDA approval" is non-infringing activity); *Merck KGAa*, 545 U.S. at 202 (the safe harbor extends to "all uses" reasonably related to the development of any information for FDA purposes).

It is undisputed that as of the time of TCT Conference, Meril had taken significant steps towards obtaining FDA approval for the Myval System, including: (1) preparing a formal clinical trial synopsis for its Landmark Trial, Mayer Reply Decl. Ex. 9;[3] (2) preparing a draft presubmission to seek FDA input on its clinical trial, Dkt. No. 84-4 ("Nair Depo.") at 33:3-24; (3) communicating with the FDA regarding Meril's proposed clinical study and its presubmission, Lad Decl. Exs. A, B; and (4) hiring an FDA consultant to help with the FDA presubmission. Lad Decl. ¶¶ 8-9; Nair Depo. at 57:10-58:15. Plaintiff does not dispute these facts, and instead contends that because Meril never actually used the devices after their importation, its safe harbor defense fails as a matter of law.

[3] The Landmark Trial appears to be a post-EU-approval study to be conducted in Europe to compare the Myval System to other leading devices in the European market. Lad Decl. ¶¶ 12, 15. Plaintiff contends that the Landmark Trial is not an "FDA clinical trial" because Meril's early documents describe it as an "outside the US" trial. Opp. at 17. However, it is undisputed that FDA approval can be supported by clinical trials that include patients both within and outside of the US. Mayer Reply Decl. Ex. 14 at 1, 4; Lad Decl. Ex. A at MERIL00000442-443. Therefore, even if the Landmark Trial was an entirely "OUS" study at the time of the TCT Conference, and even if Meril was only identifying investigators at the TCT Conference for this OUS trial, and even if it was commercially motivated in part, the Landmark Trial was reasonably related to FDA approval.

The Court finds that the undisputed evidence gives rises to no genuine dispute of fact as to whether Meril's transportation of non-commercial Myval Samples to the TCT Conference is exempt under the safe harbor. Lad Decl. ¶¶ 13-15, 17.[4] It is undisputed that Meril transported the medical device to the TCT Conference, which was attended by a large number of potential clinical trial investigators. Lad Decl. ¶ 14. It is also undisputed that Meril did not sell or offer to sell its medical device at the medical conference. *Id.* ¶ 15. Therefore, Meril's transportation of the Myval Samples to the TCT Conference, where Meril did not sell or offer to sell the device, was reasonably related to the submission of information to the FDA, including educating the investigators at the TCT about the Myval System. *See id.* ¶¶ 13, 15; *Telectronics II*, 982 F.2d at 1523 (nonsale "demonstrations constitute an exempt use reasonably related to FDA approval"); *Intermedics II*, 1993 WL 87405, at *3 (nonsale demonstrations at medical conferences are reasonably related to FDA approval and exempt under the safe harbor); *see also Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1263 (Fed. Cir. 2008) ("demonstrating an implantable defibrillator at medical conference was 'reasonably related' to FDA approval because it facilitated the selection of clinical trial investigators").

ii. University of Washington Study

Meril similarly contends that its shipment of Myval Samples to UW for preclinical investigations was protected under the safe harbor. It is undisputed that the UW preclinical study investigated whether the Myval System could be safely implanted in human subjects in future clinical studies. Bhatt Decl. ¶ 4. Plaintiff appears to agree that the UW study was performed by "an internationally respected interventional cardiologist," who successfully implanted the Myval THV in cadavers and documented the entire procedure on video. Opp. at 20; Bhatt Decl. ¶ 4;

[4] Plaintiff objects to portions of the Lad Declaration and contends that Mr. Lad lacks personal knowledge of "Meril's purpose for importing the Myval Device." Opp. at 15. However, it is undisputed that Mr. Lad personally transported the Myval Samples to the TCT Conference, and he testified that he consulted with counsel and Mr. Bhatt about bringing the Myval System to the TCT Conference. Lad Decl. ¶ 13; Lad Depo. at 34:8-34:17; 60:2-61:7. In addition, Mr. Lad and Mr. Bhatt explain that Meril brought the Myval samples to the TCT Conference to identify FDA clinical trial investigators. *See* Bhatt Depo. at 64:1-65:1, 65:21-66:10; Lad Depo. at 83:16-84:1; *see also* Bhatt Decl. ¶ 5; Stephens Decl. Ex. 13 at 6:8-11. Accordingly, Plaintiff's objections to the Lad Declaration are overruled, and Mr. Lad's declaration adequately establishes personal knowledge. *See Fraser v. Goodale*, 342 F.3d 1032, 1036 (9th Cir. 2003).

Bhatt Depo. at 40:11-20.

The Supreme Court has made clear that preclinical studies appropriate for submission to the FDA during the regulatory process are protected under the safe harbor, even if the results are never ultimately submitted. *Merck KGaA*, 545 U.S. at 202, 205 ("There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included."). Meril presents undisputed evidence that the Myval Samples were related to determining the feasibility and safety of using the Myval System to implant the Myval transcatheter valve in live human subjects, which Meril needed to confirm before it could conduct clinical trials. *Id.* at 193 (safe harbor exempts preclinical studies pertaining to device safety and efficacy in humans); *Genentech, Inc. v. Insmed Inc.*, 436 F. Supp. 2d at 1095 (applying safe harbor where third-party consultant research using the accused compound "was for FDA purposes" and where, "[w]ithout FDA approval, Defendants could not sell their drug on the market"); *Intermedics I*, 775 F. Supp. at 1285 (where safety certification by a third party was required to conduct FDA clinical tests, such testing was protected by safe harbor).

It is also undisputed that the UW clinicians used the Myval System to place a Myval THV in a cadaver. Bhatt Decl. ¶ 4. And Meril used the data collected during this investigation to understand the mechanics of positioning the Myval transcatheter valve in a human body. *Id.* There is also no dispute that, to receive premarket approval for Myval, Meril needed to first obtain an IDE from the FDA, and that the FDA requires the IDE application to include a "report of prior investigations [that] must include reports of all prior clinical, animal, and laboratory testing of the device." Lad Decl. ¶ 5; Mayer Decl. Ex. 4 at MERIL00000542; *see* Opp. at 19. Therefore, the Court finds that there is no genuine dispute that the UW preclinical study produced (and was therefore reasonably related to) the types of information that are relevant to the FDA approval process.

Plaintiff nevertheless contends that "Meril did not submit any information from this study in connection with either of its FDA pre-submissions." Opp. at 20. Meril counters that Plaintiff misunderstands the FDA process, and that Meril is only at the presubmission stage of the FDA

process, during which it is getting FDA input on certain information it plans to submit in its later IDE. Bhatt Depo. at 128:25-129:12; Mayer Reply Decl. Ex. 12. When Meril reaches the IDE stage, the FDA rules require Meril to submit the UW cadaver study video as part of its IDE. Mayer Decl. Ex. 4 at MERIL00000542. In any event, the Supreme Court has made clear that the safe harbor applies to preclinical studies even if the data is not ultimately submitted to the FDA, so Plaintiff's argument fails as a matter of law. *Merck*, 545 U.S. at 207 (safe harbor "does not become more attenuated (or less reasonable) simply because the data from that experiment are left out of the submission . . . to the FDA").

Plaintiff also contends that Meril did not describe "what information the cadaver study would generate that is relevant to an IDE or PMA." Opp. at 19. However, Meril explained that it used the data collected during the UW preclinical study to understand the mechanics of positioning the Myval THV in the human body and to determine the feasibility of safely implanting the valve in live human subjects. Bhatt Decl. ¶ 4. Plaintiff does not dispute this, and it is undisputed that the UW study data must be submitted to FDA. In the end, Plaintiff's argument is unpersuasive, and no more is required for the safe harbor to apply on this record.[5]

Lastly, leaving no potentially saving angle unexplored, Plaintiff also asserts that there were a number of additional importations as to which Defendants did not move for summary judgment. Opp. at 18-19. Defendants also appear to move for summary judgment as to the Skirball Study only in their Reply, as there is no mention of the study in the motion. Reply at 6.

However, none of these "additional" importations or acts of infringement, including the Skirball Study, are mentioned by Plaintiff in its Amended Complaint, which only addresses the UW study and the TCT Conference. *See, e.g.*, Dkt. No. 51 at ¶¶ 38-40. Although Plaintiff did include boilerplate language saying that "Plaintiffs believe that the factual contentions set forth in

[5] That Meril discussed the UW preclinical study in a Continuing Medical Education presentation in Kolkata, India two years later does not alter the applicability of the safe harbor. *See* Bhatt Dec., Ex. AA. The Federal Circuit has repeatedly explained that subsequent disclosure or use of information from preclinical or clinical studies—even for commercial purposes—does not negate application of the safe harbor. *See Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 898 (Fed. Cir. 2015) ("subsequent disclosure or use of information obtained from an exempt clinical study, even for purposes other than regulatory approval, does not repeal [the safe harbor] exemption of the clinical study").

this claim for relief will likely have further evidentiary support after a reasonable opportunity for further investigation or discovery," *id.* at ¶¶ 86, 94, this is insufficient to properly plead some unspecified number of additional unnamed potential acts of infringement. Therefore, it is immaterial whether Defendant sought summary judgment as to these unasserted theories. Accordingly, while the Court declines to grant summary judgment as to these acts based on an argument first raised in Defendant's reply, the Court finds that the additional purported acts of infringement are not presently before the Court in this action. *Hauschild v. City of Richmond*, No. C 15-01156 WHA, 2016 WL 3456620 at *5 (N.D. Cal. June 14, 2016) (disregarding "Plaintiff's new theory" in a motion for summary judgment where the complaint did not put defendants on notice about the evidence it would need to defend against plaintiff's new allegations) (citing *Pickern v. Pier 1 Imports (U.S.), Inc*., 457 F.3d 963, 969 (9th Cir. 2006) (affirming grant of summary judgment in favor of defendant where "the complaint gave the Appellees no notice of the specific factual allegations presented for the first time in [plaintiff's] opposition to summary judgment.")); *see also Bell v. F.D.I.C.*, No. C09-0150RSL, 2011 WL 2011497 at *3 (W.D. Wash. May 23, 2011) ("This claim was not asserted in the Amended Complaint, however, and cannot be added to this litigation in response to a summary judgment motion."); *Gilmour v. Gates, McDonald and Co.*, 382 F.3d 1312, 1314–15 (11th Cir. 2004) ("[T]he Supreme Court has mandated a liberal pleading standard for civil complaints … This standard however does not afford plaintiffs with an opportunity to raise new claims at the summary judgment stage … At the summary judgment stage, the proper procedure for plaintiffs to assert a new claim is to amend the complaint in accordance with Fed.R.Civ.P. 15(a).").[6]

[6] In any event, Plaintiff only relies upon a customs declaration for the simulator that lists "Navigator." Reply at 14; Stephens Decl. Ex. 26. This "Navigator" refers to a modified device that is built into the simulator and that is missing the balloon portion. Mayer Reply Decl. ¶ 34. The Court fails to see the relevance of Plaintiff's argument when the referenced "Navigator" lacks an "inflatable balloon" as required by Plaintiff's patent claims. As to the Skirball Study, it is undisputed that the study was a preclinical study to investigate Myval System's performance and to inform the feasibility of future clinical trials in live human subjects. Opp. at 4; Stephens Decl. Ex. 13 at 4:8-15; Bhatt Depo. at 84:15-20. And it is clear that Defendants provided the relevant discovery surrounding the Skirball Study. Mayer Reply Decl. ¶ 31. Accordingly, it appears that the safe harbor would also apply to the Skirball Study for the same reasons the Court has found it applies to the UW study, namely that the FDA requires Meril to submit all Myval preclinical studies—including the Skirball study—with Meril's IDE.

B. Commercial Purpose

Plaintiff contends that the safe harbor also does not apply because Meril had a commercial purpose when it brought the Myval samples to the UW and to the TCT Conference. Defendants contend that Plaintiff's argument fails for two reasons: (1) Defendants' purported purpose is irrelevant to whether the accused use falls within the scope of Section 271(e)(1), and (2) even if Defendants' purpose was relevant, Meril's purpose in transporting the samples into the U.S. in 2017 and 2019 was to support future clinical trials to seek premarket approval from the FDA.

As discussed above, whether the safe harbor applies turns on the objective question of whether the actions taken with respect to a device are reasonably related to FDA approval, and the only relevant acts are those that would otherwise constitute patent infringement under Section 271. *Eli Lilly*, 496 U.S. at 663 (inquiry is whether the safe harbor "renders activities that would otherwise constitute patent infringement noninfringing"). If Defendants' otherwise infringing act is reasonably related to FDA approval, the safe harbor applies regardless of the purported purpose behind the use. *Momenta Pharm.*, 809 F.3d at 619.

In *Abtox*, the Federal Circuit affirmed the grant of summary judgment of non-infringement, even though plaintiff asserted that the infringing activity was driven by commercial purposes. 122 F.3d at 1027. The plaintiff alleged that the safe harbor did not apply because the defendant's actual purpose behind the testing was to "promote the [device] and other equipment to potential customers" and to offer it for sale. *Id.* The Federal Circuit rejected this argument, explaining that "section 271(e)(1) requires only that the otherwise infringing act be performed 'solely for uses reasonably related to' FDA approval." *Id*. at 1030. "The statute, therefore, does not look to the underlying purposes or attendant consequences of the activity . . . , as long as the use is reasonably related to FDA approval." *Id.* Because the device testing (the allegedly infringing act there) was reasonably related to obtaining FDA approval, the safe harbor applied, regardless of defendant's intent or purpose. *Id.* Therefore, the court's safe harbor analysis focused on uses, not "purposes" or "motives." *Id*. at 1278, 1280 ("Congress did not intend the availability of the exemption to turn on findings about a party's 'purposes' or 'motives'"); *see also Genentech*, 436 F. Supp. 2d at 1095 (even if accused experiments were conducted in part for "commercial reasons," the safe harbor

applied because "the experiments would produce information that would be given to the FDA in order to get FDA approval").

Similarly, Plaintiff contends that *Amgen Inc. v. Hospira, Inc*., 944 F.3d 1327 (Fed. Cir. 2019), stands for the proposition that that commercial intent can be probative of whether an activity is "reasonably related" to regulatory uses. Opp. at 12. In *Amgen*, a jury instruction correctly instructed the jury to focus on the allegedly infringing activity and whether that activity was reasonably related to the development and submission of information to the FDA. 944 F.3d at 1338-39 ("The jury instructions properly asked whether . . . each accused activity[] was for uses reasonably related to submitting information to the FDA."). Hospira objected to part of the jury instruction, which stated that "[i]f Hospira has proved that the manufacture of a particular batch was reasonably related to developing and submitting information to the FDA in order to obtain FDA approval, Hospira's additional underlying purposes for the manufacture and use of that batch do not remove that batch from the Safe Harbor defense." *Id*. at 1338. In finding no legal error with this jury instruction, the Federal Circuit in *Amgen* affirmed that "*underlying purposes do not matter* as long as Hospira proved that the manufacture of any given batch of drug substance [the accused activity] was *reasonably related to developing information for FDA submission*." *Id*. at 1339 (emphasis added).

Given this guidance from the Federal Circuit, the safe harbor inquiry here focuses only on Meril's allegedly infringing acts, specifically (1) shipping the Myval Samples to UW; and (2) transporting the Myval Samples to the TCT Conference. As discussed above, both acts fall squarely within the safe harbor. Transportation of the Myval Samples to UW was an exempt act because it generated preclinical data to support Meril's clinical trials. Likewise, transportation of the Myval Samples to the TCT Conference (with no sales or offers for sale) was an exempt act because Meril is a sponsor "responsible for selecting qualified investigators and providing them with the necessary information to conduct clinical testing." *Telectronics II*, 982 F.2d at 1523 (citing 21 C.F.R. § 812.40). "[Meril's] intent or alternative uses are irrelevant to its qualification to invoke the section 271(e)(1) shield." *Abtox*, 122 F.3d at 1030. Accordingly, Defendants' underlying purposes are not relevant to the safe harbor inquiry, and the Court finds that

Defendants' transportation of the Myval System and Myval Samples to UW and the TCT conference fell within the safe harbor, such that there is no infringement.[7]

C. Rule 56(d) Motion

Plaintiff contends that there is an incomplete record regarding Meril's purportedly infringing acts, and that Meril's witnesses testified regarding plans surround the Landmark Trial, while Meril refused to produce documents relevant to this purported plan from earlier than May 2019.

A party seeking relief under Rule 56(d) must show "(1) that they have set forth in affidavit form the specific facts that they hope to elicit from further discovery, (2) that the facts sought exist, and (3) that these sought-after facts are essential to resist the summary judgment motion." *State of Cal., on Behalf of Cal. Dept. of Toxic Substances Control v. Campbell*, 138 F.3d 772, 780 (9th Cir. 1998). Plaintiff must have also diligently pursued the requested discovery. *See Conkle v. Jeong*, 73 F.3d 909, 914 (9th Cir. 1995).

In December 2019, Plaintiff served its first set of written discovery seeking broad categories of documents relating to all clinical trials for Myval. Mayer Reply Decl. ¶ 12. In April 2020, Plaintiff served a second set of written discovery, this time seeking broad categories of documents relating to the Landmark Trial. *Id.* ¶ 19. The parties met and conferred in late June, but it appears Plaintiff waited until July 27 to provide Meril with a draft motion to compel, which it filed after business hours on July 30, one business day before the first scheduled deposition. *Id.* Magistrate Judge Westmore denied Plaintiff's motion, holding that it was "unreasonable" to expect the Court to resolve the dispute on the "eve of deposition." Dkt. No. 77.

Plaintiff's failure to diligently pursue discovery is a sufficient basis to deny the Rule 56(d) motion. *Zamora v. City of Oakland*, No. 12-cv-02734 NC, 2013 WL 4103109, at *4 (N.D. Cal. Aug. 12, 2013) (plaintiff's failure to timely move to compel is ground for denying Rule 56(d) motion). Plaintiff contends that the majority of Meril's document production came after Meril

[7] Because intent and alternative uses are not relevant to the application of the safe harbor once it is determined that the allegedly infringing acts were reasonably related to FDA approval, the Court need not reach the issue of Meril's alleged commercial intent. *See Abtox*, 122 F.3d at 1030; *Amgen*, 944 F.3d at 1339.

moved for summary judgment, Opp. at 21, 25, but this appears to be a result of the Court's adoption of Plaintiff's proposed briefing schedule, which provided for subsequent written discovery after Meril moved for summary judgment. *See* Dkt. Nos. 52, 60; Mayer Reply Decl. ¶ 22. Finally, the timing of Meril's five document productions prior to the depositions also appears to be due, in part, to Plaintiff's delay. For example, on May 27, 2020, Meril disclosed the date ranges Meril used to search ESI and informed Plaintiff that Meril did not agree with Plaintiff's proposed date ranges. Mayer Reply Decl. ¶ 25, Ex. 23. Plaintiff did not raise this issue with Meril until July 15, 2020. Dkt. No. 72.

Accordingly, the Court **DENIES** Plaintiff's Rule 56(d) motion.

D. Motions to Seal

Meril seeks to seal a number of documents because they contain, characterize, or refer to highly confidential business information. In the Ninth Circuit, a party seeking to file documents under seal in connection with a dispositive motion must establish compelling reasons for doing so to rebut the presumption against public access. *See Foltz v. State Farm Mut. Auto. Ins. Co*., 331 F.3d 1122, 1136 (9th Cir. 2003). The Court will address each request briefly in turn.

i. Dkt. No. 66

Meril seeks to seal certain limited portions of Exhibits A and B to the Lad Declaration; the entirety of Exhibits C, D, I, and K to the Lad Declaration; certain limited portions of Meril's Corrected Memorandum of Law in support of the Summary Judgment Motion; and certain limited portions of the Lad Declaration. These documents contain sensitive proprietary information concerning Meril's clinical and regulatory strategies for the Myval System. The Court finds that this information is proprietary and meets the standard to file under seal. *See, e.g. Lucas v. Breg, Inc*., No. 15-cv-00258-BASNLS, 2016 WL 5464549, at *2 (S.D. Cal. Sept. 28, 2016) (sealing 510(k) premarket submission to the FDA addressing safety and effectiveness of device); *United States ex rel. Ruhe v. Masimo Corp*., No. 10-cv-08169-CJC(VBKx), 2013 WL 12131173, at *2 (C.D. Cal. Aug. 26, 2013) (internal research studies and clinical tests for developing the accused device, and non-public data submitted to the FDA in the course of regulatory approval, were "confidential, proprietary, and [ ] valuable"); *In re Incretin-Based Therapies Prods. Liab. Litig.*,

No.13md2452 AJB (MDD), 2015 WL 11658712, at *3 (S.D. Cal. Nov. 18, 2015) (sealing confidential and proprietary information relating to the "development, testing, and regulation" of proposed drugs, the disclosure of which would result in "significant competitive harm"); *Biovail Labs., Inc. v. Anchen Pharm., Inc*., 463 F. Supp. 2d 1073, 1083 (C.D. Cal. 2006) ("indisputable" that information contained in abbreviated new drug application to the FDA constituted trade secrets, the disclosure of which to a competitor would be "extremely damaging"). Accordingly, the Motion to Seal (Dkt. No. 66) is **GRANTED**.

ii. Dkt. Nos. 81 and 87

Plaintiff also seeks to file under seal certain information designated by Meril as "HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY" under the Protective Order applicable in this case. Specifically, Plaintiff seeks to file under seal certain limited portions of Edwards' Opposition brief; certain limited portions of the Declaration of Matthew Stephens in Support of Edwards' Opposition; and the entirety of Exhibits A-E, K, 10, 13, 19, 21-23, 25-26, 29, 36-38, 40, 43-44, 47-48, 50, 51, 53, 55, and 57-59 to the Declaration of Matthews Stephens in Support of Edwards' Opposition. Plaintiff requests that the Court grant this administrative motion to the extent Defendants' information qualifies as "privileged, protectable as a trade secret, or otherwise entitled to protection under the law." However, the parties' designations alone are insufficient to meet the compelling reasons standard, and the Court therefore **DENIES** this request to seal. Dkt. No. 81.

In light of this, Defendants filed a motion to seal (Dkt. No. 87) to identify the limited items it seeks to seal, and to provide a revised proposed order and redacted documents reflecting these changes. Meril seeks to now seal the entirety of Exhibits A, B, C, E, K, 29, 36, 38, 43-44, 47-48, 50-51, 53, 55, 57-59 to the Declaration of Matthew Stephens In Support of Plaintiff's Opposition ("Stephens Declaration"; Dkt. No. 82-1). Meril contends that these documents contain sensitive proprietary information concerning Meril's clinical and regulatory strategies for its Myval System and its business strategies concerning trade shows. Meril also moves to file the following items under seal with more limited redactions than proposed in the prior motion to seal: certain limited portions of Exhibit D and 13 to the Stephens Declaration, and certain limited portions of

Plaintiff's Opposition brief and the Stephens Declaration that describe or reference the confidential documents as summarized above. These documents also contain sensitive proprietary information concerning Meril's clinical and regulatory strategies for its Myval System and its business strategy for trade conferences.

For the foregoing reasons, the Court finds that this information is proprietary and meets the standard to file under seal, and the Motion to Seal (Dkt. No. 87) is **GRANTED**.

iii. Dkt. No. 89

Finally, Meril seeks to seal certain limited portions of Exhibits 5, 7 and 8 to the Mayer Reply. Decl., the entirety of Exhibits 9-12 and 15 to the Mayer Reply Declaration, and certain limited portions of Meril's Reply. Meril contends that these documents contain sensitive proprietary information concerning Meril's clinical and regulatory strategies for the Landmark Trial, a clinical trial for Meril's proprietary Myval transcatheter heart valve and delivery system.

Exhibit 9 is an internal draft of Meril's trial synopsis for the Landmark Trial; Exhibits 10 and 11 are communications with clinical investigators regarding the design of the Landmark Trial; Exhibit 12 is Meril's supplemental presubmission to the FDA for the Landmark Trial as part of its process of receiving FDA approval for the Myval System; and Exhibit 15 is a report for a pre-clinical study for the Myval System. Exhibits 5, 7, and 8 are excerpts of deposition testimony that also describe Meril's confidential strategies for obtaining FDA approval for the Myval System. Exhibits 5, 7, and 8 also contain confidential business strategies for engaging clinicians at trade shows, which also meet the *Foltz* standard.

For the foregoing reasons, the Court finds that this information is proprietary and meets the standard to file under seal, and the Motion to Seal (Dkt. No. 89) is **GRANTED**.

IV. CONCLUSION

For the reasons discussed above, the Court **GRANTS** Defendants' Motion for Summary Judgment, and **GRANTS IN PART** and **DENIES IN PART** the Motions to Seal.

The claim construction hearing set for November 6, 2020 is **VACATED**. The Court **SETS** a further case management conference for November 3, 2020 to discuss the plan for promptly resolving the remaining causes of action. The parties shall file a case management statement, including a proposed case schedule, no later than October 27, 2020.

IT IS SO ORDERED.

Dated: October 16, 2020

HAYWOOD S. GILLIAM, JR.
United States District Judge

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

EDWARDS LIFESCIENCES CORPORATION, et al.,

Plaintiffs,

vs.

MERIL LIFE SCIENCES PVT. LTD., et al.,

Defendants.

Case No. 4:19-cv-06593-HSG

ORDER DENYING DEFENDANTS' MOTION TO DISMISS PATENT INFRINGEMENT CLAIMS

Re: Dkt. No. 22

Pending before the Court is defendants' Meril Life Sciences Pvt. Ltd. and Meril, Inc.'s (collectively, "Defendants") motion to dismiss plaintiffs' patent infringement claims. Dkt No. 22 ("Mot."). The Court finds this matter appropriate for disposition without oral argument and the matter is deemed submitted. *See* Civil L.R. 7-1(b). After carefully reviewing and considering the parties' arguments, the Court **DENIES** Defendants' motion to dismiss.

I. BACKGROUND

Plaintiffs Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, "Edwards") develop and supply devices for the treatment of heart disease, including artificial heart valves. Dkt. No. 1 ("Complaint") ¶ 5. Defendant Meril Life Sciences PVT. Ltd. ("Meril") is an Indian company that markets "Myval"-branded transcatheter aortic valves in India and Europe. *Id.* ¶ 27. Meril distributes Myval valves as part of the "Myval System." *Id.* ¶ 32. According to the Complaint, Meril does not have FDA approval to market the Myval System in the United States and has not yet sought such approval. *Id.* ¶ 33. Meril, Inc. ("Meril USA") is Meril's United States subsidiary. *Id.* ¶ 27.

In September 2019, officers of both Meril and Meril USA attended the 2019 Transcatheter

Cardiovascular Therapeutics Conference ("TCT Conference") in San Francisco, California. *Id.* ¶ 34. Meril exhibited its Myval System at the TCT conference and then publicized its exhibition on its LinkedIn page. *Id.* ¶ 35 (stating that Meril's booth at the conference "exhibited the MeRes100 and Myval TAVR system"). Edwards now claims that Meril infringed its patents under 35 U.S.C. §§ 271(a) and (g) by importing its patented invention and devices made using its patented process into the United States. *Id.* ¶¶ 35, 54-70. Edwards also claims that both Meril and Meril USA infringed its trademarks and engaged in unfair competition. *Id.* ¶¶ 71-86.

II. LEGAL STANDARD

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint must contain sufficient factual matter to state a claim for relief that is "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim has facial plausibility "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Warren v. Fox Family Worldwide, Inc.*, 328 F.3d 1136, 1139 (9th Cir. 2003). To evaluate plausibility, a court must "accept factual allegations in the complaint as true and construe the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). However, a court "need not accept as true conclusory allegations that are contradicted by documents referred to in the complaint." *Id.* Materials outside of the pleadings may not be considered unless (1) they are incorporated into the complaint and their authenticity is not disputed, or (2) they are subject to judicial notice. *Lee v. City of Los Angeles*, 250 F.3d 668, 688-89 (9th Cir. 2001).

III. DISCUSSION

Defendants argue that Edwards failed to state a claim for patent infringement because the only act of infringement alleged in the complaint—exhibiting the accused device at a medical conference—is protected by the safe harbor of 35 U.S.C. § 271(e)(1). Section 271(e)(1) provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Congress enacted section 271(e)(1) to streamline the process of obtaining FDA approval for generic drugs. *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1272 (N.D. Cal. 1991). Prior to the provision's enactment, clinical testing necessary to obtain FDA approval could not begin until after the expiration of the branded drug's patent term, artificially extending the patent monopoly and delaying the entry of generic drugs. *Id*. at 1272-73. To address this problem, section 271(e)(1) provided a safe harbor for otherwise infringing acts performed "solely for uses reasonably related to the development and submission of information to the FDA." *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1261 (Fed. Cir. 2008) (quoting 35 U.S.C. § 271(e)(1)). The safe harbor has been extended to medical devices and other products subject to FDA approval. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-74 (1990). Section 271(e)(1) thus allows a competitor to begin obtaining FDA approval during the lifetime of a patent in order to begin selling the competing product immediately upon the patent's expiration.[1] *Proveris*, 536 F.3d at 1261.

The section 271(e)(1) exemption provides a "wide berth" for activities related to regulatory approval and "extends to all uses . . . that are reasonably related to the development and submission of *any* information under the FDCA." *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). Neither the stage of the research nor the outcome of the activities matters. *Id.* The safe harbor applies even if the clinical studies failed or the research results were never submitted to the FDA, as long as the researcher had "a reasonable basis for believing" that the activity would yield information appropriate for submission to the FDA. *Momenta Pharma., Inc. v. Amphastar Pharma., Inc.*, 686 F.3d 1348, 1356-57 (Fed. Cir. 2012). Nor does it matter that the accused infringer had additional, non-regulatory purposes for the activity—"[a]s long as the activity is reasonably related to obtaining FDA approval," the court "does not look to the underlying purposes or attendant consequences of the activity." *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997); *see also Momenta Pharma., Inc. v. Teva Pharma. USA Inc.*, 809

[1] To ensure that the patent holder benefited from the entire term of the patent, Congress also extended patent terms by five years for a patented product "subject to a regulatory review period before its commercial marketing or use" where that use represented "the first permitted commercial marketing or use of the product." *Eli Lilly*, 496 U.S. at 671.

F.3d 610, 619 (Fed. Cir. 2015) ("The breadth of the exemption extends even to activities the 'actual purpose' of which may be 'promotional' rather than regulatory, at least where those activities are 'consistent with the collection of data necessary for filing an application with the [FDA] . . . for approval.").

Not all activities performed prior to FDA approval, however, fall within the exemption. *Amgen Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 852 (Fed. Cir. 2009). In *Amgen*, the Federal Circuit considered whether clinical experiments conducted after data had been submitted to the FDA qualified for the exemption. *Id*. at 852. Although regulatory approval had not been granted, and supplemental submission was possible, the court found that the exemption might not apply because evidence suggested that some studies were conducted at the request of the marketing department for purposes of brand recognition. *Id*. at 853-53. Citing *Merck* for the proposition that "[e]ach of the accused activities must be evaluated separately," the court determined that "factual questions of the purposes" of the challenged activities had to be evaluated regardless of the nature and stage of the activity. *Id*. (citing *Merck*, 545 U.S. at 200); *accord Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1339-41 (Fed. Cir. 2019) (affirming jury finding that drug batch manufacture during FDA approval fell outside the safe harbor because evidence showed it was not required and was intended for commercial inventory).

Defendants contend that the accused devices were imported into the United States for display at a medical conference in order to identify or recruit clinical investigators who could perform studies required by the FDA. Defendants cite three cases to argue that such conference displays constitute an "exempt" use under section 271(e)(1). First, in *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, the Federal Circuit granted summary judgment in favor of the accused infringer who demonstrated a patented device at a medical conference allegedly to obtain clinical investigators for FDA trials. 982 F.2d 1520, 1523 (Fed. Cir. 1992). The court held that "[a]bsent some showing that Ventritex's purpose is disputed, such demonstrations constitute an exempt use reasonably related to FDA approval" because "device sponsors are responsible for selecting qualified investigators and providing them with the necessary information to conduct clinical testing." *Id*. Any incidental demonstrations to non-physicians did not defeat this finding

because "only physicians can implant the device." *Id*. Second, in two unpublished dispositions—*Intermedics, Inc. v. Ventritex Co., Inc.* and *Chartex International PLC v. M.D. Personal Products Corp.*—the Federal Circuit affirmed district courts' grant of summary judgment exempting conference displays based on *Telectronics*. 991 F.2d 808, 1993 WL 87405, at *3 (Fed. Cir. 1993); 5 F.3d 1505, 1993 WL 306169, at **2-3 (Fed. Cir. 1993). Edwards responds that the section 271(e)(1) safe harbor inquiry is "inherently factual" and not properly resolved on a motion to dismiss. The complaint alleges that Defendants imported the accused devices for commercial promotion of their sales in Europe and had not sought FDA approval in the United States—rendering any recruitment of clinical investigators unrelated to FDA approval.

The Court is not convinced that *Telectronics* and its progeny establish a "per se" rule that obviates the need for any further factual inquiry. As an initial matter, all three cases Defendants cite were decided on summary judgment, not motions to dismiss. *Telectronics* expressly qualified its holding by noting the absence of any "showing that Ventritex's purpose is disputed."[2] 982 F.2d at 1523. Moreover, the district court in *Intermedics* performed an extensive factual examination of the use of conference displays for recruitment, and based its conclusion in part on the lack of dispute. *See Intermedics*, 775 F. Supp. at 1287 (finding factually undisputed that medical conference help recruit investigators and determining that it was "reasonable" for defendants to believe the display would lead to generation of data for submission to the FDA). None of these cases dealt with a factual disagreement regarding whether medical conference displays reasonably led to recruitment of clinical investigators for FDA studies. The procedural posture of these cases thus cautions against deciding the applicability of the section 271(e)(1) exemption on a motion to dismiss.

Moreover, applying a "per se" rule exempting conference displays from infringement would conflict with the directive of *Merck* and *Amgen* that "[e]ach of the accused activities must be evaluated separately." *See Amgen*, 565 F.3d at 852. An activity may be "reasonably related" to

[2] *Telectronics* was decided prior to *Abtox*, which held that subjective purpose is irrelevant for the section 271(e)(1) exemption. The court in *Telectronics* appeared to have considered subjective purpose and may have found it dispositive.

regulatory submissions in some factual circumstances, but not others. *E.g.*, *Merck*, 545 U.S. at 205-06 (finding that scientific research may or may not fall within the exemption depending on the circumstances). Although Defendants are correct that subjective purpose is not dispositive, a commercial intent may nevertheless be probative of whether an activity is "reasonably related" to regulatory uses. *Amgen*, 944 F.3d at 1340 (finding no error where jury considered commercial intent as probative—but not dispositive—of whether activity related to FDA approval); *see also Amgen*, 565 F.3d at 852 (noting "factual questions of the purposes" of challenged activities in reversing safe harbor finding). Here, Edwards alleges that Defendants displayed the accused device in order to promote their commercial sales in Europe.[3] Complaint ¶¶ 33, 35. Neither the complaint nor any document subject to judicial notice establishes that Defendants recruited (or reasonably could have recruited) investigators for studies leading to information that could be submitted to the FDA. Accepting all factual allegations in the complaint as true and drawing inferences in favor of the plaintiff, Defendants have not shown that the section 271(e)(1) exemption applies.[4]

Defendants additionally argue that Edwards' lawsuit is premature because the FDA has not yet granted approval to the accused device, which may still change during the approval process. Although the Federal Circuit has previously exempted "*de minimis*" infringement from patent damages, the rule has been narrowly circumscribed to very specific circumstances. *See Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000). Now, even a single act of infringement suffices for Edwards to seek damages against the Defendants, even if that act is commercially minor and not likely to repeat in the future. Defendants' cited cases, which addressed the "case or controversy" requirement in declaratory judgment actions, do not apply because Edwards indisputably has standing to bring its lawsuit.

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[3] Edwards requests judicial notice of additional documents suggesting a commercial intent behind Defendants' TCT conference display. Dkt. No. 27. Because this decision does not rely on these materials, the Court **DENIES** the request for judicial notice as moot.

[4] Defendants suggest that because they could not legally begin promoting their products prior to FDA approval, they could not have done so at the conference. The question of whether Defendants complied with the statute, however, has no bearing on the exemption. Moreover, the act of importation may constitute patent infringement even if no commercialization takes place.

Accordingly, the Court **DENIES** Defendants' motion to dismiss. The Court further **SETS** an initial case management conference for February 25, 2020, at 2:00 p.m. The parties need not submit a further joint case management statement.[5]

IT IS SO ORDERED.

Dated: February 18, 2020

HAYWOOD S. GILLIAM, JR.
United States District Judge

United States District Court
Northern District of California

[5] Edwards sought leave to file a sur-reply containing certain allegedly confidential information. Dkt. No. 36. The Court denied the motion. Dkt. No. 38. Because the Court denied leave to file the sur-reply, the public's interest in accessing the cited documents is minimal. *See In re iPhone Application Litig.*, No. 11-MD-02250-LHK, 2013 WL 12335013, at *2 (N.D. Cal. Nov. 25, 2013). Accordingly, the Court **GRANTS** Edwards administrative motion to file under seal. Dkt. No. 35.

FORM 31. Certificate of Confidential Material **Form 31**
July 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF CONFIDENTIAL MATERIAL

Case Number: 22-1877

Short Case Caption: Edwards Lifesciences Corporation v. Meril Life Sciences Pvt. Ltd.

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Date: 09/22/2022

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Name: Christy G. Lea

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Counsel for Appellants Edwards Lifesciences Corporation and Edwards Lifesciences LLC certifies that the brief contained herein has a proportionally spaced 14-point typeface and contains 10,797 words, based on the "Word Count" feature of Word version Office365, including footnotes and endnotes. Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b), this word count does not include the words contained in the Certificate of Interest, Table of Contents, Table of Authorities, Abbreviations, and Statement of Related Cases.

DATED: September 22, 2022 By: */s/ Christy G. Lea*
Christy G. Lea

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